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The Environmental Fate and Effects Division (EFED) has completed the ecological effects and environmental fate preliminary risk assessment to be conducted as part of the registration review of the insecticide pirimiphos-methyl for its registered uses with cattle eartags and for post harvest stored corn and sorghum grain treatments. An evaluation of ecological risk to aquatic and terrestrial organisms as a result of the use of pirimiphos-methyl is summarized in the Executive Summary and the Risk Characterization sections of the attached document. A separate document containing a problem formulation was prepared for pirimiphos-methyl (DP Barcode No. 362650, dated March 9, 2009, Regulations.gov Document ID EPA-HQ-OPP-2009-0056). Details related to the Nature of the Regulatory Action (Section 2), Findings from Previous Risk Assessments (Section 2), Nature of the Chemical Stressor (Section 3), Use Characterization (Section 3), and Conceptual Model and Risk Hypothesis (Section 6) are discussed in this cited document.

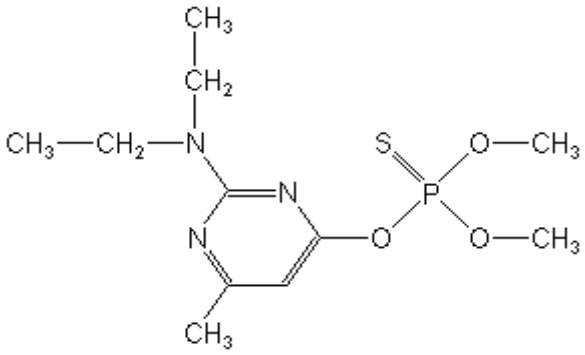
For post-harvest stored grain uses, exposure is very limited given the nature of application occurring as the grain is stored a long time before the replanting of treated seeds in the field. Therefore, risks of concern are not expected for the post-harvest stored grain uses of pirimiphos-methyl. However, while the exposure scenario associated with replanting treated seed is expected to be most prevalent, EFED recommends to address potential pirimiphos-methyl treatments to corn and sorghum grain stored at locations other than indoor storage bins, such as outdoor bunkers, on

the Actellic® and Execute® labels to further minimize the potential for exposure in the environment.

For cattle eartag uses, risks of concern leading to adverse impacts are not identified for any aquatic or terrestrial taxa considering its usage limited to pasture use sites. The number of treated cattle anticipated at a pasture site, does not result in any risk within the terrestrial environment about the treatment site or within nearby water bodies. Pirimiphos-methyl is not widely used at feedlots since infestations of its targeted pests, horn flies (*Haematobia irritans)* and face flies *(Musca autumnalis*) are not anticipated at these use sites.

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Preliminary Environmental Fate and Ecological Risk Assessment for the Registration Review of Pirimiphos-methyl



O-(2-Diethylamino-6-methylpyrimidin-4-yl) O,O-dimethyl phosphorothioate

(Pirimiphos-methyl, CAS 029232-93-7)

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1. Executive Summary

This document contains the environmental fate and ecological risk assessments for the registered uses of the organophosphate chemical pirimiphos-methyl [O-(2-Diethylamino-6-methylpyrimidin-4-yl) O,O-dimethyl phosphorothioate].

Pirimiphos-methyl was originally introduced in the United States in 1984[1]. There are a number of active Section 3 products containing pirimiphos-methyl that include post-harvest treatment of corn or sorghum seeds and grain for immediate storage as well as treated ear tag products applied to beef and non-lactating dairy cattle or calves. Pirimiphos-methyl ear tags ultimately result in residues being absorbed by the hide of cattle. There are also two special local needs Section 24(c) labels. The Washington State label is for indoor fogger treatment on iris bulbs. Michigan labeled uses include dip and drench treatment to gladiola bulbs and indoor fogger treatment for gladiola bulbs. According to Office of Pesticide Programs Information Network (OPPIN), cancellation is pending for the Michigan label.

Post harvest Stored Grain Uses

For pirimiphos-methyl post harvest stored grain uses, it was previously concluded in the Problem Formulation (DP Barcode 362650, dated March 9, 2009) and reaffirmed in this assessment, that aquatic and terrestrial exposure resulting from the treated seed storage is limited considering the small application rate made to grain as well as the long interval between time of treatment and planting of the treated seeds. Therefore, risks of concern are not expected for the post-harvest stored grain uses of pirimiphos-methyl. However, while the exposure scenario associated with replanting treated seed is expected to be most prevalent, EFED recommends to address potential pirimiphos-methyl treatments to corn and sorghum grain stored at locations other than indoor storage bins, such as outdoor bunkers, on the Actellic® and Execute® labels to further minimize the potential for exposure in the environment.

Eartag Uses

The conceptual model in this risk assessment identifies the main potential for exposure to aquatic organisms associated with pirimiphos-methyl eartags uses resulting from wash off of residues and subsequent runoff to aquatic environments from cattle eartag applications. These applications are mainly expected to occur at pastureland use sites and not at feedlots (refer to the Use Characterization Section in **Section 2** for a further description). The main uncertainties that exist for this scenario are the amount of cattle simultaneously treated with eartags at a given use site and the washoff fraction from cattle hide resulting from rainfall occurring concurrent with pirimiphos-methyl treatment. As a result of these uncertainties, risk quotients (RQs) were not estimated in this assessment as they would be in a deterministic fashion for conventional uses (*i.e.* foliar spray). Instead, this risk assessment addresses these uncertainties by utilizing a bracketing approach exploring numbers of cattle treated that would indicate a risk concern to aquatic organisms over a range of washoff fractions to determine the level pirimiphos-methyl treatment causing a concern.

[1] http://pmep.cce.cornell.edu/profiles/insect-mite/mevinphos-propargite/pirimiphos-methyl/insect-prof-actellic.html

The screening aquatic exposure model, the GENeric Estimated Exposure Concentration model (GENEEC) is used as the basis of the bracketing analysis described above, to assess runoff from a generic 10-hectare treated use site to a 1-hectare pond. The Pesticide in Water Calculator (PWC), which is normally used to assess runoff of pesticide residues for cropped fields, is not employed in this assessment given unique eartag treatment. The adverse impacts analysis initially incorporates the GENEEC estimated exposure concentration (EEC) in surface water normalized to one head of treated cattle. Then, available acute toxicity data for freshwater fish and freshwater invertebrates are incorporated to determine the number of head of treated cattle meeting and exceeding the levels of concern (LOCs) threshold for aquatic species. Additionally, the level of washoff or washoff fraction to result in adverse impacts to aquatic taxa is determined. As is discussed and justified in **Section 4.3**, the combined residues of parent pirimiphos-methyl along with the residues of O-2 diethylamino-6-methylpyrimidin-4-yl o-methyl-phosphorothioate (hereafter referred to as degradate No.2) will be considered the stressor of concern for ecological risk assessment purposes. The final results with the bracketing analysis are presented in **Table 9**.

The results with the number of heads of cattle causing concern at certain levels of washoff fractions of residues presented in **Table 9** are put into perspective with the density of cattle at expected at potential pastureland use sites in Risk Description Section (**Section 5.2)**. **In general, adverse impacts to aquatic organisms from washoff of residues from pirimiphos-methyl eartags are not expected considering that much of its use occurs at sites with small cattle inventories.** While adverse impacts to listed aquatic invertebrates may occur with 5 percent of residues from eartags washing off into water bodies at feedlot sites keeping 40 head of cattle or less, it is not expected that this level of washoff would occur considering the expected reduction in environmental loading from factors such as its semi-volatile nature and propensity for delayed rainfall events during treatments not captured in this assessment. These uncertainties, discussed further in **Section 6**, provides further insights that a small portion of residues (less than 5 percent) are likely to washoff and end up in water bodies nearby pirimiphos-methyl eartag use sites, and therefore not result in risks of concern for aquatic orgnaisms.

It is worth noting that only acute freshwater fish and invertebrate toxicity data is available. However, given the toxicity that is established with organophosphate (OP) insecticides to aquatic taxa, similar effects and thresholds will be assumed for estuarine/marine fish and invertebrates when used in proximity to these environments. No data are available to characterize the chronic toxicity of pirimiphos-methyl to aquatic species. It is an uncertainty as to what level of washoff would be needed to yield effects to growth or reproduction on fish or aquatic invertebrates. Additionally, no data are available to characterize the subchronic and chronic toxicity of pirimiphos-methyl to sediment dwelling invertebrates. Environmental fate data indicate pirimiphos-methyl has a propensity to partition to the sediment based on its range of K_d values (15.6 – 161.9 mL/g) and moderately high log K_{OW} value of 4.2.

Additionally, no data are available for vascular or non-vascular aquatic plants or terrestrial plants. Pirimiphos-methyl is highly toxic to adult honey bees on an acute contact and acute oral basis as would be anticipated from an organophosphorus (OP) insecticide. There are no data to characterize the acute and chronic oral toxicity to honey bee larvae. Available data indicate pirimiphos-methyl is highly toxic to birds on an acute oral and subacute dietary basis, however, as

indicated previously, the extent as to the magnitude of residues this taxa as well as mammals would be exposed to is an uncertainty.

There are also more general uncertainties as to the extent that terrestrial organisms would be exposed as a result of the cattle eartag use. Pirimiphos-methyl does show high levels of toxicity to birds on an acute oral and subacute dietary basis although toxicity is lower for mammals on an acute oral basis as compared to birds. The literature shows that some species of birds and mammals are not only present in feedlots[2], but also may be responsible for the spread of certain diseases in cattle feedlots such as *E. coli* and *Salmonella*[3]. Because there are toxic effects to taxa confirmed to be present in pastureland use sites the estimation of a dose or concentration that would be available to these taxa is necessary but difficult with standard approaches. As pirimiphos-methyl does not have spray or granular uses, simulating exposure estimation with the Terrestrial Exposure Model (T-REX) is not feasible. Additionally, any exposure of pirimiphos-methyl to these taxa would likely originate from the eartags falling off of the cattle, a scenario that this assessment assumes is not frequent.

2. Use Characterization

In this document, only the most pertinent details regarding the Use Characterization are briefly summarized below. **Section 3.3** of the original problem formulation document can be referred to for further details.

Pirimiphos-methyl uses encompass six active registrations. The labels by FIFRA classification are summarized below:

- Four Section 3 labels, and
- Two Special Local Needs (Section 24c) labels

Uses for the Section 3 pirimiphos-methyl registrations include cattle eartag uses (for lactating and beef cattle) and post-harvest stored grain seed treatments for corn and sorghum seeds. Eartags contain up to 3.84 grams a.i. per animal (or 1.92 grams a.i. per eartag). For post-harvest seed treatments, up to 0.12 lbs a.i. per 1,000 square feet of grain may be applied. There are no restrictions for where pirimiphos-methyl can be used nationwide.

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[2] Palmer, Thomas K. 1976. "Pest Bird Damage Control in Cattle Feedlots: The Integrated Systems Approach." *Proceeedings of the 7th Pest Vertebrate Conference,*. Available online at: http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1035&context=vpc7&sei-redir=1&referer=http%3A%2F%2Fscholar.google.com%2Fscholar%3Fhl%3Den%26as_sdt%3D0%2C9%26q%3Dbirds%2Band%2Bmammals%2Bin%2Bcattle%2Bfeedlots#search=%22birds%20mammals%20cattle%20feedlots%22

[3] Gaukler, Shannon M et al. (2009). "Escherichia coli, Salmonella, and Mycobacterium avium subsp. Paratuberculosis in Wild European Starlings at a Kansas Cattle Feedlot." *Avian Diseases*, 53(4):544-551. Available online: http://lib.dr.iastate.edu/cgi/viewcontent.cgi?article=1040&context=vmpm_pubs&sei-redir=1&referer=http%3A%2F%2Fscholar.google.com%2Fscholar%3Fq%3Dbirds%2Band%2Bmammals%2Bin%2Bcattle%2Bfeedlots%2Band%2Be%2Bcoli%26btnG%3D%26hl%3Den%26as_sdt%3D0%252C9#search=%22birds%20mammals%20cattle%20feedlots%20e%20coli%22

Special Local Needs uses include indoor fogger treatments using pirimiphos-methyl for ornamental bulbs in Washington State and Michigan. Up to 0.224 lbs. a.i. per 1,000 cubic feet of space may be applied for these uses.

There are no restrictions related to the use sites where pirimiphos-methyl can be used. In addition, for pirimiphos-methyl eartag uses, the maximum quantity of cattle treated or the maximum frequency of application per use site is not specified on product labels.

Discussion of Eartag Use Sites

Potential pirimiphos-methyl use sites for cattle eartags, based alone on areas where cattle reside associated with commercial livestock production operations, may include pasture sites, rangeland, and feedlots. Out of all of these use sites, the feedlot use site is expected to possess the highest concentration of cattle by far. According to USDA's Feedlot Report from 2011[4], small feedlots equal to or less than 1,000 head of cattle accounted for the vast majority of sites accounting for 97.1 percent of feedlots nationwide, while larger feedlots only accounted for 2.8 percent of total sites. While widely variable, pasture and rangeland sites are expected to possess concentrations of cattle at far less head per acre than at feedlots, most of which contain no more than 1,000 head of cattle.

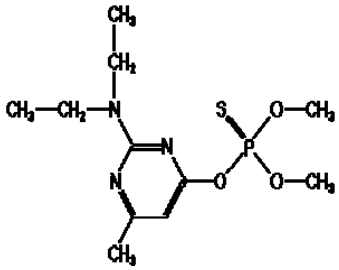
However, while feedlots may appear to be a vulnerable use site related to insecticidal eartag use based on cattle density as described above, there is evidence to suggest that feedlots are not areas where eartags are used frequently, if at all, considering that pirimiphos-methyl eartags are used to control infestations of horn fly and face fly pests. Feedlots are generally not recognized as suitable habitats to maintain sustainable populations of horn flies and face flies since these insects require stagnant soils and fresh manure for their reproduction cycles with incubation of fly larvae. To this point, the dense presence of cattle is known to generate large and constant turnover of soil and manure matter at feedlots. Therefore, horn fly and face fly infestations and related pirimiphos-methyl eartag usage are expected to be most common at pasture and rangeland sites as opposed to feedlot sites. This information is conveyed by multiple state agricultural extension services (e.g., Alabama, Mississippi, Kentucky, and Nebraska) where eartag usage is common or where feedlots are present (refer to Section 9 for complete citations).

3. Exposure Characterization

Registrant-submitted data defining the physical, chemical, fate and transport characteristics associated with pirimiphos-methyl are summarized in **Table 1**. As part of registration review, available environmental fate studies for pirimiphos-methyl have been reevaluated. The fate and transport of pirimiphos-methyl in the environment is discussed below.

[4] Full Citation:.U.S. Department of Agriculture (USDA). 2011. Feedlot 2011 Report, Part I: Management Practices on US Feedlots with a Capacity of 1,000 or More Head. United States Department of Agriculture. Available online at:. http://www.aphis.usda.gov/animal_health/nahms/feedlot/downloads/feedlot2011/Feed11_dr_PartI.pdf. Accesed December 2015.

Table 1. General physical-chemical and environmental fate properties of pirimiphos-methyl.

Chemical/Fate parameter	Value	Source (MRID)	Study Acceptability
Physical Chemical Properties			
Chemical Structure and SMILES Code	 CCN(CC)c1nc(C)cc(OP(=S)(OC)OC)n1	Product Chemistry (MRID 00129333	N/A
Molecular Weight (g/mol)	305	Product Chemistry (MRID 00129333)	N/A
Vapor Pressure (torr at 30°C)	1.1×10^{-4}	Product Chemistry (MRID 00129333)	N/A
Octanol-water Partition Coefficient (Log K_{OW} at 20°C)	4.2	Product Chemistry (MRID 92147003)	N/A
Octanol-air Partition Coefficient (Log K_{OA})	8.743	EPI Suite (KOAWIN v. 1.1 estimate)	N/A
Water Solubility (mg/L; at 20°C)	9.9 mg/L at pH 5.2 8.6 mg/L at pH 7.3 9.3 mg/L at pH 9.3	Product Chemistry (MRID 92147003)	N/A
Henry's Law Constant (atm-m^3 mol^{-1})	5.105×10^{-6}	EPI Suite (HENRYWIN v. 3.10)	N/A

Chemical/Fate parameter	Value	Source (MRID)	Study Acceptability
Soil-water partition coefficients (K_d)	England Soils[5]: LS1: 15.6 mL/g (OC = 1.60%) LS2: 27.4 mL/g (OC = 1.69%) LS3: 32.7 mL/g (OC = 2.97%) S: 11.6 mL/g (OC = 0.29%) SiCL: 161.9 mL/g (OC = 1.63%) SL: 45 mL/g (OC = 1.92%)	MRID 48355601	**Supplemental:** • Significant degradation was observed in low pH soils (S, SiCL, SL)
Abiotic Degradation[1]			
Hydrolysis half=lives (days)	7.3 days at pH 5 79 days at pH 7 54 – 62 days at pH 9[2]	MRID 42982401 MRID 43177601	**Acceptable**
Aqueous photolysis half-life (days at 20°C) [3]	0.2 days	IUPAC Pesticide Properties Database[6]	N/A
Photolysis in air half-life (hours at 25°C)	2.4 hours 0.802 hours	SRC Database EPI Suite (AopWIN v. 1.92)	N/A
Soil Photolysis half-life (days)	No Data Available	-	N/A
Biotic Degradation[1]			
Aerobic Soil Metabolism half-life ($t_{1/2}$ in days)	England Soils[5]: SL1: 33.6 days (OC = 3.70%, pH7.1) SL2: 28.7 days (OC = 1.00%, pH6.6) L: 42.7 days (OC = 6.0%, pH7.5) P: 31.5 days (OC = 36.2%, pH6.0)	MRID 135358	**Supplemental:** • Potential degradation associated with the extraction procedures not addressed. • Pertinent test conditions (e.g., temperature and moisture content) throughout the studies not reported.
Anaerobic Soil Metabolism half-life (days) [4]	England Soils[5]: SL1: 36.4 days (OC = 3.7%, pH7.1) L: 31.5 days (OC = 6.0%, pH7.5)		
Aerobic Aquatic Metabolism half-life (days)	No Data Available	-	N/A
Anaerobic Aquatic Metabolism half-life (days)	No Data Available	-	N/A
Field Studies			

Chemical/Fate parameter	Value	Source (MRID)	Study Acceptability
Terrestrial Field Dissipation	No Data Available	-	N/A
Bioaccumulation			
BCF Fish	274X	SRC Database EPI Suite (WSKOW v. 1.42)	N/A

[1] Half-lives based on first order rate constant, k ($t_{1/2}$ = ln2/k) derived from Time – Ln(Concentration) regression.
[2] Half-life range at pH9 among multiple replicates reported.
[3] Estimated based on DT-50 value.
[4] Half-life ranges based on replicates with flooded water soil atmosphere reported.
[5] Soil texture identifiers: SLn: Sandy loam replicate, LSn: Loamy sand replicate, L: Loam, P: Peat, SiCL: Silty Clay Loam
[6] Available on-line: http://sitem.herts.ac.uk/aeru/iupac/

3.1 Transport and Dissipation Pathways

The measured soil-water partition coefficients (K_d) for pirimiphos-methyl residues range between 11.6 mL/g to 161.9 mL/g. These measured partition coefficients in soil are poorly correlated to organic carbon content (r^2 = 0.012). The water solubility limit of pirimiphos-methyl ranges between 8.6 to 9.9 mg/L. Both pirimiphos-methyl's values of solubility and sorption coefficients indicate that pirimiphos-methyl residues will partition both to the sorbed phase and dissolved phase in soil and aquatic sediment. Therefore, pirimiphos-methyl can be transported to offsite water bodies via runoff and erosion processes.

The vapor pressure of 1.1 x 10^{-4} torr suggests that pirimiphos-methyl can exist in the vapor-phase. However, the photolysis in air half-life of between 0.802 and 2.4 hours suggests that the residence time of pirimiphos-methyl vapors in air will be limited. Furthermore, no VOCs (including vapor-phase pirimiphos-methyl) were detected in any volatile trap in the aerobic and anaerobic soil metabolism studies summarized above in **Table 1**. The screening analysis presented in **Section 3.4** verifies that pirimiphos-methyl exposure via the air and inhalation exposure pathway is not of concern.

3.2 Degradation

The major degradation pathway for pirimiphos-methyl O-(2-Diethylamino-6-methylpyrimidin-4-yl) O,O-dimethyl phosphorothioate) is hydrolysis, especially in acidic environments. Hydrolysis half-lives from laboratory studies ranged from 7.3 days at pH 5, to 79 days at pH 7 with a half-life of 54 – 62 days at pH 9. In acidic environments, the major degradate was 2(diethylamino)-4-hydroxy-6-methyl pyrimidine (hereafter referred to as degradate no. 1). In the pH 5 solution, degradate no. 1 reached maximum levels up to 87.3 days post treatment of the overall material balance. In neutral and alkaline environments, degradate no. 1 was also found at major levels along with the degradate no. 2 (exact chemical name defined in the executive summary of this document). In the pH 7 solution, degradate nos. 1 and 2 reached maximum levels of 22.5 % and

26.5% of the overall material balance at 90 days post-treatment, respectively. In the pH 9 solution, degradate no. 1 and 2 reached levels of 21.0 and 18.2%, respectively of the overall material balance. Degradate no. 1 did not retain the organophosphate (P=S bond) linkage, whereas degradate no. 2 did.

Aqueous photolysis is also expected to be a significant degradation process for pirimiphos-methyl with an experimentally-determined DT_{50} of 0.2 days. Pirimiphos-methyl is also expected to be photolabile in air, with experimentally determined half-lives ranging between 0.802 – 2.4 hours (see **Table 1** above).

Pirimiphos-methyl degradation in soil occurs at similar rates and appears to be mediated by hydrolysis, with half-lives ranging between 28.7 – 42.7 days in four soils. The major metabolite from aerobic and anaerobic soil metabolism is degradate no. 1 (defined above) which formed at levels up to between 37 – 66% of applied. Major levels of unextractable residues consistently occurred throughout all tested soils, in the range of up to 28.2 – 66.3% of the applied material, and a nonpolar extraction solvent was not used to extract residues partitioned to soil. However, given pirimiphos-methyl's high sorption to soil (see **Section 3.1** above) and partially thorough extraction method utilizing acetone followed by methanol extraction solvents, residues appear to be bound to sediment. No Agency guideline studies have been conducted to determine the biodegradation of pirimiphos-methyl in water or its dissipation in the field.

Degradate no. 1 did not maintain the organophosphate moiety (P=S bond) and is not expected to possess toxicity exceeding that of parent pirimiphos-methyl. However the organophosphate moiety was maintained with degradate no. 2. Therefore, the potential for toxicity exists with degradate no.2. Please refer to **Appendix E** for further information on the formation of degradates, and **Table 8 of Section 4.3** supporting the findings on the toxicity of the degradates relative to parent-pirimiphos-methyl.

3.3 Bioaccumulation

A log K_{ow} of 4.2 indicates that pirimiphos-methyl is sufficiently hydrophobic for binding to fatty tissue for aquatic organisms as well as available sediment. While there are no BCF in fish studies available, a regression K_{ow} –based model suggests that the BCF value for pirimiphos-methyl is approximately 274X in aquatic organisms. This BCF further indicates the high potential for pirimiphos-methyl residues to build up in the tissues of aquatic biota.

3.4 Exposure Pathways

Pirimiphos-methyl and its organophosphate demethylated degradate [degradate No. 2] are considered to be the primary stressors in this risk assessment. The degradate formed at major levels of up to 26.5% of applied due to hydrolysis (at pH7). For further information on the formation of degradates please refer to **Appendix E**. Furthermore, the degradate's toxicity is likely similar to the parent compound given its similar organophosphate moiety. Please refer to **Table 8 of Section 4.3** supporting the findings on the toxicity of the degradates relative to parent-

pirimiphos-methyl. Given the similar moieties between parent pirimiphos-methyl and the degradate, this risk assessment will use a total toxic residues approach in exposure estimates assuming equal toxicity for both constituents.

Potential exposure to aquatic and terrestrial organisms with pirimiphos-methyl exists only with cattle eartag and post-harvest grain seed treatment uses. There is no ecological risk associated with the indoor fogger treatment to iris included in the Washington State Section 24(c) label and the indoor fogger, dip, and drench treatments to gladiola bulbs in the Michigan Section 24(c) label.

The identification of relevant environmental exposure pathways to pirimiphos-methyl applications for this risk assessment evaluating impact to non-target organisms are discussed below:

- **Aquatic Exposure**: Pirimiphos-methyl may impact ***aquatic environments*** after off-site movement mainly from pasture use sites associated with ***cattle ear tag uses*** for lactating and beef cattle. Pirimiphos-methyl residues from treated cattle with eartags may washoff from treated cattle and become embedded within runoff in an accumulated form from pastures. Freshwater and estuarine marine fish and invertebrates as well as aquatic plants in the water column may be impacted. In addition, benthic organisms residing in the bottoms of water bodies may also be impacted given pirimiphos-methyl's tendency to partition to sediment. Refer to **Section 3.5** of this document for the aquatic exposure assessment. **Section 3.5** describes the use of GENEEC to evaluate pirimiphos-methyl cattle treatments at pasture use sites.

  Given pirimiphos-methyl's low application rates with ***post-harvest stored grain seed treatments***, there is a smaller potential for exposure resulting from runoff of pirimiphos-methyl residues to nearby water bodies associated with this use pattern. Nonetheless, this exposure pathway was evaluated in Attachment A in the original problem formulation document (DP Barcode No. 362650, dated March 9, 2009). Please refer to this document for further details.

- **Dietary Exposure**: ***Birds and mammals*** can potentially be impacted through dietary routes resulting mainly from pirimiphos-methyl ***post-harvest stored grain seed treatment*** residues. Pirimiphos-methyl residues may be bioavailable on harvested corn and sorghum seeds which are harvested, treated during storage, and then re-planted the next season. The dietary exposure analysis for pirimiphos-methyl was completed in a memo responding to a waiver request for an avian reproduction study (DP Barcode 357626, dated February 18, 2011). The analysis using the T-REX model (version 1.4.1, 12/07/2006) showed that there were no adverse impacts associated with post-harvest seed treatment uses for pirimiphos-methyl and therefore this pathway will not be further addressed in this assessment. This model has since been updated to version 1.5.2 (06/11/2013) but the conclusions remain the same. Please see the data waiver response memo for details. T-REX is publically available at the following website:
  http://www.epa.gov/oppefed1/models/terrestrial/trex/t_rex_user_guide.htm

  Furthermore, ***piscivorous birds and mammals*** feeding on contaminated fish may potentially be exposed with pirimiphos-methyl residues bioavailable from exposed aquatic organisms

primarily due to washoff and subsequent runoff associated with ***eartag uses***. Bioaccumulation of pirimiphos-methyl residues is possible in fish given pirimiphos-methyl's Log K_{ow} value of 4.2. There is no quantitative method available to evaluate this route of exposure for the eartag use. The K_{OW}-based Aquatic BioAccumulation (KABAM, v.1.0) model is available but without all necessary inputs available. Please see the Risk Description section for an analysis with KABAM using conservative assumptions. Fixed equivalent maximum application rates cannot be defined with eartag uses given the nature of this use pattern and information available on labels. The application rate is a key factor for determining the amount of pirimiphos-methyl residues bioavailable to piscivorous birds since it largely impacts the water body concentrations which can be expected. Please refer to the Risk Description Section (**Section 5.2**) for further discussion regarding risks which may occur resulting from this exposure pathway as well as a description of the uncertainties which exist related to this exposure pathway for pirimiphos-methyl.

- **Terrestrial plants and Terrestrial Invertebrates:** Sporadic and low density of pirimiphos-methyl residues are expected on pasturelands with cattle treated are expected. As eartag uses are not associated with a foliar spray, there would be no drift expected from these uses of pirimiphos-methyl. Therefore, exposure to terrestrial plants and terrestrial invertebrates which forage on and around plants will be limited.

- **Drinking water exposure**: An analysis using the Screening Imbibition Program (SIP version 1.0, 6/15/2010) indicated that drinking water exposure alone is not a potential concern for mammals on an acute basis. Conversely, exposure though drinking water alone is a potential concern for mammals on a chronic basis as well as for birds on an acute basis. As an avian reproduction study is not available for pirimiphos-methyl, risk could not be precluded from the model. There is currently no refinement in the risk assessment process to further characterize the likelihood of this exposure pathway being complete or the relative risk associated with this pathway. It is an uncertainty whether significant residues of pirimiphos-methyl would exist in puddles present in feed lots as well as the frequency to which birds and other mammals visit these feed lots to potentially be exposed through drinking water. SIP is available publically at:
  http://www.epa.gov/oppefed1/models/terrestrial/sip/sip_user_guide.html

- **Inhalation exposure to terrestrial animals:** The potential for pirimiphos-methyl inhalation exposure only exists via the vapor-phase. Inhalation to spray droplets would not exist for pirimiphos-methyl since it is not applied in a spray form for eartag and seed treatment uses. The STIR model is used to initially evaluate this exposure pathway. The Screening Tool for Inhalation Risk (STIR, version 1.0; 11/23/2010)model relies on user-inputs of vapor pressure as well as mammal inhalation, mammal oral, and inhalation oral toxicity data to determine need to address the inhalation exposure pathway in the risk assessment. The results of STIR, indicate the need to proceed to further refinements only for birds, as indicated by the ratio of vapor dose to adjusted inhalation LD_{50} is a value that indicates the need to proceed to refinements. STIR may be accessed on-line at:
  http://www.epa.gov/oppefed1/models/terrestrial/stir/stir_user_guide.html

- The likelihood of exposure via inhalation for birds can be explored further using the Health

Effects Division (HED) Tier 1 Air Exposure Model (Tool Developed by Chuck Peck, version 1, dated 7/22/13). However, it should be noted that this model accounts for vapor-phase release from soil surfaces, and can depict the potential release of pirimiphos-methyl from the grounds of pasturelands after it washes off from eartags. Since no off-gasing data are available for pirimiphos-methyl from eartags, exposure resulting from pirimiphos-methyl's release from soil can only be assessed. As such, this exploration will conservatively assume that 100 percent of pirimiphos-methyl are available to off-gas from the grounds of pastures after washoff from the eartags. The HED Tier 1 Air Exposure Model contains additional physical chemical properties such as vapor pressure, solubility, and soil-water partition coefficients to determine the upper-bound volatile flux rate of pirimiphos-methyl from soil. This flux rate is carried over to EPA's AERSCREEN dispersion model to determine the resulting vapor-phase estimated exposure concentration (EEC) in air. Given the equivalent avian LC_{50} value of 930.75 $\mu g/m^3$ in air estimated from STIR[5] for birds and air EEC 43.48 $\mu g/m^3$ (equivalent to a risk quotient of 0.05), a more refined analysis for inhalation exposure of pirimiphos-methyl released from soil in the vapor-phase is not needed.

The analyses using the STIR model and HED Tier 1 Air Exposure model is presented in detail in **Appendix C**.

3.5 Aquatic Exposure Analysis

Post-Harvest Stored Grain Seed Treatment Uses

Please refer to **Attachment A** of the original problem formulation document (DP Barcode No. 362650, dated March 9, 2009) for the evaluation of aquatic exposure resulting from post-harvest seed treatment uses of pirimiphos-methyl. Upper-bound estimated exposure concentrations (EECs) in surface water were calculated using the pe5 shell for the PRZM/EXAMS model, ranging up to 0.002 µg/L.[6]

Cattle Ear Tag Uses

Attachment B of the original problem formulation document also presented a preliminary analysis of aquatic exposure occurring from ear tags. However, the exposure analysis is updated in this risk assessment. The exposure analysis presents an evaluation of the number of heads of treated cattle leading to adverse impacts (*i.e.*, LOC exceedances) rather than deterministic risk quotients

[5] The equivalent avian inhalation endpoint of 930.75 $\mu g/m^3$ is calculated from the dose-based adjusted avian inhalation LD_{50} of 0.468 mg/kg-bw determined from STIR (see **Table C.1**, **Appendix C**). The conversion is shown as follows, based on equation 9 within the STIR User's Manual:
$LC_{50} = LD_{50}$ adjusted / (Abs x CF x D x A)] x 1,000 L/m^3 x 1,000 µg/mg= 930.75 $\mu g/m^3$
where LD_{50} adjusted = 0.468 mg/kg-bw, Abs (chemical absorption into tissue) = 1.0, D (exposure duration) = 4 hours, A (animal activity factor at rest) = 1.0, CF {conversion factor = [avian inhalation rate (2,514.1 cm^3/hr) x 0.001 L/cm^3]/body weight (0.02kg)} = 502.82 L/hr

[6] It should be noted that K_d/K_{oc} and aerobic soil metabolism half-lives inputs used in the exposure analysis for post-harvest seed treatments in the problem formulation were different from the analysis with eartag uses presented in this document considering the preliminary review status of environmental fate studies at that time. However, all inputs utilized in the problem formulation result in a conservative assessment of exposure.

based on an exposure scenario for which ecotoxicological data are available (freshwater fish and invertebrates). This approach captures of range of outcomes possible associated with potential aquatic exposure with pirimiphos-methyl eartag usage while considering two major uncertainties: 1.) The amount of cattle that is simultaneously treated with pirimiphos-methyl, and 2.) The amount washoff or washoff fraction from the treated cattle to the feedlot, which is then available for runoff to nearby water bodies.

Since runoff of pirimiphos-methyl is being evaluated, aquatic exposure models can be used to evaluate the amount of pirimiphos-methyl eartgas that would be required to runoff in sufficient quantities to trigger adverse impacts to listed and non-listed aquatic species. The screening aquatic exposure model GENEEC (latest version dated 10/10/14, developed by Ron Parker) is used for this evaluation given that it uses a runoff scenario (modified to exclude spray drift) from a generic 10-hectare treated area to a 1-hectare pond. The Surface Water Concentration Calculator (SWCC), which is normally used to assess runoff of pesticide residues for cropped fields, is not employed in this case given the unique use pattern for eartags. The adverse impacts analysis incorporates the GENEEC estimated exposure concentration (EEC) in surface water normalized to one head of treated cattle and available acute toxicity data for freshwater fish and freshwater invertebrates to determine the number of head of treated cattle meeting and exceeding the acute listed and non-listed levels of concern (LOCs) for aquatic species. This analysis is presented in **Section 5.1**.

The exposure analysis for pirimiphos-methyl use at pastureland use sites will evaluate the potential exposure which occurs from heads of cattle treated simultaneously. It will be assumed that each head of cattle possesses two eartags containing 1.92 grams a.i. each for a total of 3.84 grams (8.47×10^{-3} lbs.) total of pirimiphos-methyl as permitted by the label. From this scenario, an application rate can be calculated with the initial assumption that the total amount of pirimiphos-methyl washes off from the treated cattle, is available for runoff, and that the resulting residue will be evenly distributed with the 10-hectare treated pasture. From these assumptions, an equivalent application rate normalized to one head of treated cattle can be calculated considering the 3.84 grams (8.47×10^{-3} lbs.) of pirimiphos load with each head of cattle and the 10-ha treated area. The resulting equivalent application rate is 3.43×10^{-4} lbs./A per head of cattle [8.47×10^{-3} lbs. ÷ (10 ha x 2.47 A/ha)]. Use sites larger than 10 hectares are not evaluated since the amount of treated cattle is expected to be proportional to the pasture site size impacted by runoff. Therefore, the total pirimiphos-methyl runoff mass per unit area is expected to be conserved over all pasture land use site sizes and thus the effective application rate should not be impacted.

However, the major uncertainty is the fraction of pirimiphos-methyl that could potentially wash off from treated cattle. The 3.43×10^{-4} lbs./A value is a high-end application rate assuming 100% of pirimiphos-methyl residues washes off. Therefore, this aquatic exposure analysis will use a bracketing technique, where the equivalent application rate is linearly proportional to the amount that washes off. Accordingly, the application rates for each of the washoff fractions (evaluated for 100%, 20%, 10%, 5%, and 1%) from treated cattle are shown in **Table 3.**

The remaining parameterization for GENEEC is composed of the physical chemical and fate properties of pirimiphos-methyl utilizing EFED Model Input Parameter Guidance[7]. All input parameter values for the aquatic exposure assessment for pirimiphos-methyl cattle eartags are

[7] Available on-line: http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm

shown in **Table 2.**

Table 2. Input parameter values used in GENEEC for pirimiphos-methyl adverse impacts analysis for cattle ear tag uses at pasture use sites.

GENEEC Input Parameter	Input Value and Unit	Comment	Source
Application Rate (lbs. a.i./A per head of treated cattle)	See **Table 3**	Based on 3.84 grams of pirimiphos-methyl per head of treated cattle and 10-hectare use site size for specified washoff fraction	Product label and standard runoff exposure scenario evaluated
Application Method	Broadcast[1]	No Spray Drift, Incorporated to Surface Only	Consistent with washoff scenario for eartag use
Hydrolysis ($t_{1/2}$)	198 days	Total Toxic Residue half-life including parent pirimiphos-methyl and its OP demethylated degradate (see **Section 3.2** and **Appendix E** for chemical name and identification) at pH 7	MRID Nos. 42982401 & 43177601
Aerobic soil metabolism ($t_{1/2}$)	39.1 days	Parent only, OP demethylated degradate not detected in study 90th percentile on the upper confidence bound half-life from n=4 soils (refer to **Table 1**)	MRID 135358 EFED Model Input Parameter Guidance
Aerobic aquatic metabolism ($t_{1/2}$)	Stable	Conservative assumption	-
Solubility in Water at 20ºC	8.6 mg/L	Product Chemistry	Product Chemistry (MRID 92147003)
Soil-Water Partition Coefficient (K_d)	49.03 mL/g	Average value from n=6 soils (refer to **Table 1**)	MRID 48355601 EFED Model Input Parameter Guidance
Aqueous Photolysis ($t_{1/2}$)	0.2 days	DT-50 value	IUPAC Pesticide Properties Database[2]

[1] Broadcast application method consistent with chemical distribution associated with granular application as defined in GENEEC.

[2] Available on-line: http://sitem.herts.ac.uk/aeru/iupac/

The resulting EEC normalized to one head of treated cattle for each washoff fraction evaluated is

provided in **Table 3** (see **Appendix B** for the sample GENEEC file). The EECs normalized to one head of treated cattle along with endpoints available from freshwater fish and freshwater invertebrate toxicological studies will be used to compute the number of treated cattle leading to adverse impacts resulting from eartag use. This analysis is possible since the EECs are directly proportional to the amount of cattle treated, assuming all cattle possess the same number of eartags. In this assessment, all cattle are assumed to contain two eartags, one on each ear. The normalized EECs to one head of cattle shown in **Table 3** is used to determine the amount of treated cattle leading to adverse impact. This evaluation is presented in **Section 5.1**.

Table 3. GENEEC pirimiphos-methyl surface water EECs at equivalent application rates normalized to one head of treated cattle for certain washoff fractions.

Input/Output Variable	Washoff Fraction				
	100%	20%	10%	5%	1%
Equivalent Application Rate (lbs. a.i./A per head of treated cattle)[a,b]	3.43×10^{-4}	6.85×10^{-5}	3.43×10^{-5}	1.71×10^{-5}	3.43×10^{-6}
Surface Water EECs (µg/L per head of treated cattle)[b]	2.49×10^{-3}	4.98×10^{-4}	2.49×10^{-4}	1.25×10^{-4}	2.49×10^{-5}

[a] For calculation of the equivalent application rate, please refer to the discussion above **Table 2.**
[b] Based on 10-hectare size use site.

Water Quality Monitoring Data

According to a recent search of existing monitoring databases, there are no surface water or ground water data monitoring data available for pirimiphos-methyl. However, this does not indicate that detections of pirimiphos-methyl are not possible, especially in the vicinity of pasture lands where pirimiphos-methyl is used. Rather, EFED is not aware of any attempts to measure pirimiphos-methyl in the environment. Therefore, this risk assessments relies solely on upper-bound exposure estimates provided by environmental fate and transport models such as GENEEC.

3.6 Terrestrial Exposure Analysis

Please refer to the memo that was completed in response to a waiver request related to the Avian Reproduction study (DP Barcode 357626, dated February 18, 2011) for the terrestrial exposure assessment for pirimiphos-methyl uses. This memo contains the dietary exposure analysis for pirimiphos-methyl resulting from post-harvest stored grain steed treatment use. The analysis used label information to calculate upper-bound exposure concentrations bioavailable to birds and mammals using the TREX model (version 1.3.1, 12/07/2006). This model has since been updated to version 1.5.2 (06/11/2013) but the conclusions remain the same.

As stated in **Section 3.4**., there is limited exposure to non-target terrestrial organisms associated with the cattle eartag uses of pirimiphos-methyl. It cannot be stated with certainty that non-target terrestrial organisms would not be present at a pasture use site but it is not expected that terrestrial organisms would be exposed to pirimiphos-methyl residues to a large extent. Therefore, no further analysis addressing exposure to non-target terrestrial organisms resulting from pirimiphos-methyl cattle eartag uses is presented in this risk assessment.

4. Ecological Effects Characterization

The ecological effects characterization for pirimiphos-methyl is based upon registrant-submitted toxicity data for the TGAI (parent pirimiphos-methyl) and for specified formulations.

4.1 Aquatic Effects Summary

Pirimiphos-methyl exposure effects on aquatic organisms were determined by assessing freshwater fish and freshwater invertebrates. For these two taxa, only acute exposure studies were available. There were no acute or chronic studies available for estuarine/marine fish and invertebrates nor for any aquatic plant species. Additionally, there were no data available to evaluate the subchronic and chronic toxicity of pirimiphos-methyl to sediment dwelling invertebrates. Each study's species tested, endpoint, and MRID number are tabulated below separated by taxa.

Toxicity to Freshwater Fish

There are two acute freshwater fish toxicity studies available for pirimiphos-methyl. In an acute study conducted with the rainbow trout (*Oncorhynchus mykiss*, MRID 00103924), fish were exposed to pirimiphos-methyl concentrations (88.9% purity) ranging from 0.18 to 0.75 mg a.i/L in a continuous flow-through system. Total (100%) mortality occurred at the highest treatment concentration. Clinical signs of toxicity included darkening of skin and gill inflammation but these effects were not quantified in the individual treatment concentrations. The 96-hour LC_{50} was determined to be 0.40 mg a.i/L (95% CI: 0.34 – 0.45) and this study is classified as acceptable.

In an acute toxicity study conducted with both rainbow trout and bluegill sunfish (*Lepomis macrochirus*, MRID 00103925), fish were exposed at concentrations ranging from 0.33 – 2.2 mg a.i/L and 1.0 – 4.7 mg a.i/L, respectively. There were no clinical signs of toxicity observed in the rainbow trout study but in the bluegill sunfish study, signs of toxicity included rapid jaw movements, disorientation, keeling, and gill inflammation (concentrations at which the signs were observed were not reported). The 96-hour LC_{50} values for rainbow trout and bluegill sunfish were determined to be 1.18 (0.98 – 1.47) and 2.80 (2.46 – 3.10) mg a.i/L, respectively. This study is classified as acceptable.

Table 4. Summary of Acute Toxicity Data for Freshwater Fish Exposed to Pirimiphos-methyl

Species	Study Duration (Exposure System)	Purity of Test Substance (as %)	LC_{50} (mg a.i/L)[1,2,3] (95% CI; slope)	Toxicity Classification (MRID)
Rainbow trout (*Oncorhynchus mykiss*)	96-hour (flow-through)	88.9	**0.40** (0.34 – 0.45; 8.04)	Highly toxic (00103924)

Species	Study Duration (Exposure System)	Purity of Test Substance (as %)	LC_{50} (mg a.i/L)[1,2,3] (95% CI; slope)	Toxicity Classification (MRID)
Rainbow trout	96-hour (flow-through)	84	1.18 (0.98 – 1.47; N/A)	Moderately toxic (00103925)
Bluegill sunfish (*Lepomis macrochirus*)			2.80 (2.46 – 3.10; 10.5)	

CI: Confidence interval. LC_{50}: Lethal concentration to 50% of the population. N/A = not applicable
[1]**Bolded** values represent the most sensitive toxicity endpoints for freshwater fish exposed to parent pirimiphos-methyl
[2]Based on mean measured concentrations.

There is one acute freshwater invertebrate toxicity study available for pirimiphos-methyl. In a study with *Daphnia magna* (MRID 00103926), organisms were exposed to both TGAI (99.5% purity) and formulated pirimiphos-methyl (50% purity) at varying concentrations. TGAI and formulated product exposures ranged from 0.01 – 50 µg a.i/L. There was no mention of any clinical signs of toxicity being observed throughout the study. The 48-hour EC_{50} was determined to be 0.21 µg a.i/L (0.15 – 0.31) and 0.11 µg a.i/L (0.08 – 0.15) for TGAI and formulated pirimiphos-methyl, respectively. This study was classified as acceptable for the TGAI component and supplemental for the formulated product component. The rationale for supplemental status for the formulated product component was that there was no need to cite a formulation study at the time of the review. It was further stated this classification could be upgraded to acceptable if that status changed.

Table 5. Summary of Acute Toxicity Data for Freshwater Invertebrates Exposed to Pirimiphos-methyl

Species	Study Duration (Exposure System)	Purity of Test Substance (as %)	LC_{50} (µg a.i/L)[1] (95% CI; slope)	Toxicity Classification (MRID)
Water flea (*Daphnia magna*)	48-hour (flow-through)	99.5	0.21 (0.15 – 0.31; N/A)	Very highly toxic (00103926)
		50	0.11 (0.08 – N/A)	

CI: Confidence interval. LC_{50}: Lethal concentration to 50% of the population. N/A = not applicable
[1]Based on mean measured concentrations.

4.2 Terrestrial Effects Summary

There is one avian acute oral and three avian subacute dietary studies available for pirimiphos-methyl. In an acute oral study with the northern bobwhite quail, birds were exposed to control or nominal treatment doses of 19.4, 32.4, 54, 90, 150, and 250 mg a.i/kg bw. There was total (100%) mortality in the three highest doses and 80% mortality in the 54 mg a.i./kg bw group. Clinical signs of toxicity were observed at all but the lowest treatment group (19.4 mg a.i/kg bw) that included ruffled appearance, depression, reduced reaction to external stimuli, loss of coordination, wing droop, lower limb weakness, walking stiffly, prostrate posture, shallow and rapid breathing, salivation, loss of righting reflex, minor muscle fasciculations, and muscle spasms. A marked weight loss was also observed at these treatment doses. The 14-day LD_{50} was determined to be

40 mg a.i/kg (32 – 50). This study was classified as acceptable (**Table 6**).

In a subacute dietary study with the mallard duck, birds were exposed to control or concentrations in the diet of 215, 464, 1000, 2150, and 4640 ppm. Total (100%) mortality was observed in the two highest treatment concentrations and 80% at the middle treatment concentration (1000 ppm). Clinical signs of toxicity included lethargy, labored respiration, and loss of coordination. The 8-day LC_{50} was determined to be 633 ppm (453 – 883). This study is classified as acceptable (MRID 00107422).

In a subacute dietary study with the northern bobwhite quail, birds were exposed to control or concentrations in the diet of 21, 46, 100, 215, and 464 ppm. Total (100%) morality was observed in the highest treatment concentration. Clinical signs of toxicity included wing droop, depression, loss of coordination, and loss of righting reflex. This study is classified as acceptable (MRID 00107423). In a second dietary study conducted with the mallard duck, birds were exposed to control or concentrations of 163, 325, 650, 1300, 2600, and 5200 ppm. Total (100%) mortality was observed at the four highest treatment concentrations and 60% was observed at the 325 ppm treatment concentration. Clinical signs of toxicity were observed at the five highest treatment concentrations and included subdued behavior, huddling together, unsteadiness of gait, drooped wings, and stumbling/lying on the pen floor. The 8-day LC_{50} was determined to be 284 ppm (164 – 643). This study (MRID 42037001) is classified as supplemental since there was no confirmatory analysis of concentrations in the feed was conducted.

Table 6. Summary of Acute Oral and Subacute Dietary Toxicity for Birds Exposed to Pirimiphos-methyl

Species	Study Type	Purity of Test Substance (as %)	LD_{50} (mg a.i/kg bw) or LC_{50} (mg a.i/kg diet)[1,2] (95% CI; slope)	Toxicity Classification (MRID)
Northern Bobwhite quail (*Colinus virginianus*)	Avian Acute Oral	89.8	**40** (32 - 50; 7.3)	Highly toxic (43442101)
Mallard duck (*Anas platyrhynchos*)	Subacute Dietary	Not specified (study report did indicate TGAI)	633 (453 – 883; N/A)	Moderately toxic (00107422)
Northern Bobwhite quail (*Colinus virginianus*)	Subacute dietary	Not specified (study report did indicate TGAI)	**207** (106 – 407; N/A)	Highly toxic (00107423)
Northern Bobwhite quail (*Colinus virginianus*)	Subacute dietary	89.3	284 (164 – 643; N/A)	Highly toxic (42037001)

CI: Confidence interval. LD_{50}: Lethal dose to 50% of the population. N/A = not applicable
[1]**Bolded** values represent the most sensitive toxicity endpoints for birds exposed to pirimiphos-methyl
[2]Based on mean measured concentrations.

Mammals

In an acute oral study available for pirimiphos-methyl, formulated (75.4% purity) product was administered to rats (MRID 00126257). There are no acute oral studies available for rats with technical pirimiphos-methyl. The actual treatment levels the rats were exposed to was not available in the DER and the study report was difficult to interpret. The LD_{50} was determined to be >2400 mg/kg, which classifies pirimiphos-methyl as practically non-toxic to mammals on an

acute oral basis. Clinical signs of toxicity included diarrhea, lethargy, decreased respiratory rate, and body tremors at the lowest treatment dose. There was no mortality in the lowest treatment dose and 75 and 100% mortality in the middle and highest treatment doses, respectively. This study was classified as acceptable.

In a two generation reproduction study, rats were fed diets containing technical pirimiphos-methyl (86.7% purity) at dose levels of control, 10, 40, and 160 ppm. There were no treatment related effects observed on any reproductive parameters. There was a reduction in body weight (percent effect or statistical significance not indicated in DER or study report) at the highest treatment concentration. There were sporadic findings of clinical signs of toxicity that were not associated with any one generation nor were they observed in a dose responsive manner. These included hair loss, swollen forepaw, protruding eyes, piloerection, and trembling. The most sensitive endpoint was significant ($p<0.05$) plasma cholinesterase inhibition that occurred at all treatment concentrations and therefore a definitive NOAEL could not be established.

Table 7. Summary of Acute Oral and Chronic Toxicity for Mammals Exposed to Pirimiphos-methyl

Species	Study Type	Purity of Test Substance (as %)	LD_{50} (mg a.i/kg bw) or NOAEL (effects)[1] (95% CI; slope)	Toxicity Classification (MRID)
Norway rat (*Rattus norvegicus*)	Acute oral toxicity	75.4	**>2400 (N/A; N/A)**	Practically non-toxic (00126257)
	2-generation reproduction	86.7	<10 ppm (cholinesterase inhibition)	-- (43726801)

CI: Confidence interval. LD_{50}: Lethal dose to 50% of the population. N/A = not applicable
[1]**Bolded** values represent the most sensitive toxicity endpoints for mammals exposed to pirimiphos-methyl

Terrestrial Invertebrates

There is one study available to characterize the acute contact and oral toxicity to adult honey bees. The study (MRID 05001991) tests several other chemicals and only provides the acute contact and oral LD_{50} determinations with no accompanying information on sublethal effects, confidence intervals, or any other narrative pertaining to study design and test methods. The acute contact and acute oral LD_{50} were determined to be 0.13 and 0.39 µg a.i/bee, respectively which classifies pirimiphos-methyl as very highly toxic to honey bees.

4.3 Degradate toxicity

As described in **Section 3.2**, pirimiphos-methyl is subject to degradation to various products via multiple pathways. There are no available toxicity studies to characterize the toxicity of the degradation products of pirimiphos-methyl. Therefore, the ECOSAR (v.1.1) module of EPISUITE (v.4.1) was employed to estimate the toxicity of these degradates as compared to the registrant submitted studies available for parent pirimiphos-methyl. ECOSAR uses structure activity relationships (SAR) to predict the toxicity of compounds that share similar structural moieties. For each degradate of pirimiphos-methyl, the most sensitive (*i.e.* lowest) estimate of toxicity for a given taxa was tabulated below in **Table 8**. Also shown are the ECOSAR estimates for parent

pirimiphos-methyl which corroborate the registrant submitted toxicity study for freshwater fish but under predict the toxicity to freshwater invertebrates by approximately one order of magnitude.

Environmental fate data indicate that two major (*i.e* >10% of the applied residues) degradates form in the available hydrolysis study. One degradate (degradate No.2), forming as a result of demethylated pirimiphos-methyl, preserves the organophosphate moiety of the parent compound. Accordingly, ECOSAR results shown in **Table 8** below estimates similar toxicity of this degradate to that of parent pirimiphos-methyl. A second degradate, 2(diethylamino)-4-hydroxy-6-methyl pyrmidine (degradate No. 1), which loses the organophosphate moiety, is estimated by ECOSAR to be at least three orders of magnitude less toxic to freshwater fish and invertebrates on an acute and chronic exposure basis. Please refer to **Section 3.3** and **Appendix E** on the formation of this degradate. Based on this analysis, the stressor of concern for ecotoxicological risk will be the combined residues of parent pirimiphos-methyl and its demethylated organophosphate degradate (*i.e*. degradate no. 2).

Table 8. ECOSAR predicted toxicity (mg a.i/L) of the degradates of pirimiphos-methyl

Stressor (Endpoint Source)	Endpoint (in mg a.i/L)			
	Freshwater Fish LC_{50}	Freshwater Invertebrate EC_{50}	Chronic Freshwater Fish NOAEC	Chronic Freshwater Invertebrate NOAEC
Pirimiphos-methyl (registrant submitted studies)	0.4	0.00021		
Pirimiphos-methyl (ECOSAR estimates)	0.23	0.002	0.033	0.00000007
2(diethylamino)-4-hydroxy-6-methyl pyrimidine(degradate no. 1) (ECOSAR estimates)	396	39.1	40.7	2.68
O-2 diethylamino-6-methylpyrimidin-4-yl o-methyl-phosphorothioate (degradate no.2) (ECOSAR estimates)	0.24	0.001	0.035	0.00007

4.4 ECOTOX Open Literature

Open literature studies are identified using EPA's ECOTOXicology database (ECOTOX) (USEPA, 2007*c*), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife. The evaluation of both sources of data can also provide insight into the direct and indirect effects of pesticides on biotic communities from loss of species that are sensitive to the chemicals and from changes in structure and functional characteristics of the affected communities. A search of ECOTOX in October, 2014 yielded no endpoints more sensitive than those already available.

4.5 Review of Incident Data

The ecological incident information system (EIIS) is an EFED-maintained database that houses ecological incidents that have been reported to the Agency. When available, EIIS includes date

and location of an incident, type and magnitude of effects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and results of any chemical residue analysis or other analyses conducted during incident investigation. EIIS incidents are categorized according to the certainty that the incident resulted from pesticide exposure. The OPP-maintained Incident Database System (IDS) and the Aggregate Incident Database provide incident counts at the chemical and product level but do not provide the narrative information contained in EIIS. The Avian Incident Monitoring System (AIMS) is a database administered by the American Bird Conservancy that contains publicly available data on reported avian incidents involving pesticides. Many of the incidents listed in this database are also in the EIIS. Searches of the incident databases were conducted in November, 2014.

A search of EIIS, the IDS, Aggregate Incident Database, and AIMS returned no reported wildlife incidents involving pirimiphos-methyl.

5. Risk Characterization

5.1. Risk Estimation

Aquatic Exposure: Post-Harvest Stored Grain Seed Treatment Uses

PRZM/EXAMS runs (via pe5 shell) using the Georgia Farm Pond scenario, presented in the original problem formulation document do not indicate a concern for exposure to aquatic organisms in surface water with acute (one-in-ten year peak) pirimiphos methyl surface water EECs $\leq$ 0.0018 ppb and chronic (one-in-ten year 60-day average) pirimiphos-methyl EECs $\leq$ 0.0007 ppb[8]. The EECs result in risk quotients (RQs) for acute freshwater fish of <<0.01 and <0.01 for acute freshwater invertebrates[9]. Despite pirimiphos-methyl's potential for off-site movement, the most likely reason for low EECs is the very low application rate on treated seed. It is noted that the EECs are conservative since the amount of pirimiphos-methyl available for off-site transport was based on a standard seed treatment use whereby degradation during storage time as well as release of residues from treated seeds were not taken into account. Since this analysis presented in the problem formulation did not reveal risk quotients above the level of concern, aquatic risks are not expected and therefore, are not further evaluated in this assessment.

Environmental exposure from pirimiphos-methyl grain treatments are not expected during its application since the labels instruct pirimiphos-methyl to be applied as grain is stored. The Actellic label is especially explicit restricting use-sites off of farms. EFED recommends similar explicit language for the Execute label, which is the only other product used for post harvest grain storage treatments. Furthermore, for both labels, EFED recommends restricting pirimiphos-methyl use to corn and sorghum grain that is contained indoors or otherwise in storage containers, and

[8] It should be noted that K_d/K_{oc} and aerobic soil metabolism half-lives inputs used in the exposure analysis for post-harvest seed treatments in the problem formulation were different from the analysis with eartag uses presented in this document considering the preliminary review status of fate studies at that time. However, all inputs utilized in the problem formulation result in a more conservative assessment of exposure.

[9] Based on surface water EEC and freshwater fish LC_{50} = 404 ppb (MRID No. 00103924) and freshwater invertebrate EC_{50} = 21 ppb (MRID No. 00103926).

prohibiting its use in outdoor bunkers to more explicitly ensure the intentional use of pirimiphos-methyl while minimizing exposure in the environment.

Aquatic Exposure: Cattle Ear Tag Uses

As mentioned in **Section 3.5**, this risk estimation presents an evaluation of the number of heads of treated cattle leading to adverse impacts (*i.e.*, LOC exceedances) rather than deterministic risk quotients based on an exposure scenario with a fixed assumption on the number of simultaneous treated cattle at the use site. The EECs normalized to one head of treated cattle for each washoff fraction, shown in **Table 3**, are used along with endpoints available from freshwater fish and freshwater invertebrate toxicological studies to compute the number of treated cattle leading to adverse impacts resulting from eartag use. This analysis is possible since the EECs are directly proportional to the amount of cattle treated, assuming all cattle possess two eartags. The number of treated cattle leading to adverse impacts for acute freshwater fish and acute freshwater invertebrates is presented in **Table 9.** The results presented in **Table 9** are discussed further in context with the cultural practices of cattle and pasture operations in the Risk Description section (**Section 5.2**) below.

Table 9. Summary of pirimiphos-methyl treated heads of cattle to trigger adverse impacts for listed and non-listed species on an acute basis.

Aquatic Species and Adverse Impacts Thresholds	Pirimiphos-Methyl Water Body Concentration of Concern (µg/L)	Head of Treated Cattle Causing Concern Given Washoff Fractions (number of cattle)[c]				
		100%	20%	10%	5%	1%
Freshwater Fish						
Acute Listed Species (LOC = 0.05)	20.2 [a]	8,038	40,188	80,376	160,751	803,757
Acute Non-Listed Species (LOC = 0.5)	202[a]	80,038	400,188	800,376	1,607,510	8,037,570
Freshwater Invertebrates						
Acute Listed Species (LOC = 0.05)	0.0055[b]	2	10	20	40	200
Acute Non-Listed Species (LOC = 0.5)	0.055[b]	20	100	200	400	2,000

[a] Acute concentration of concern for freshwater fish based on the following calculation: *Rainbow Trout* acute endpoint (LC_{50} = 404 µg/L) x 0.05 or 0.5 (LOCs for listed and non-listed species). *Rainbow Trout* acute endpoint from MRID No. 00103924.

[b] Acute concentration of concern for freshwater invertebrates based on the following calculation: *Daphnid* acute endpoint (EC_{50} = 0.11 µg/L) x 0.05 or 0.1 (LOCs for listed and non-listed species). *Daphnid* acute endpoint from MRID No. 00103926.

[c] Heads of Cattle Causing Concern = Concentration of Concern (µg/L) ÷ GENEEC peak EEC (µg/L) for each washoff fraction shown in **Table 3.**

Terrestrial Exposure: Post-Harvest Stored Grain Seed Treatment Uses

The registrant provided an argument on why there would be negligible exposure for terrestrial organisms resulting from the stored grain seed treatment uses of pirimiphos-methyl. These lines of evidence were originally captured in a waiver request submitted by the registrant for an avian reproduction study, contending that there would be insufficient exposure to necessitate such a test ("EFED Response to Avian Reproduction Study - OCSPP 850.2300 – Waiver Request for Pirimiphos-methyl," D357626, February 18, 2011). The main arguments were made from an absence of exposure basis (as described below), and unnecessary use of animals for toxicity testing when compared to overall value to the risk assessment.

Estimated environmental concentrations (EECs) were calculated from the highest rates on current labeled seed treatment uses for sorghum and corn (0.48 lbs a.i per 30 tons of grain, Acetallic® 5E Insecticide). The registrant provided an example where it was assumed that only 1% of the pesticide will remain on the soil surface due to spillage (Imazilil Reregistration Eligibility Decision; US EPA, 2005). However, because the application rate is so low, either 1% or 100% assumptions for seed consumption do not result in high exposure levels. The maximum exposure concentration is 2.03 mg a.i/kg-bw/day based on the assumption of 100% bioavailability following seed treatment. Therefore, maximum potential exposure levels of pirimiphos-methyl from seeds treated in the field appears to be very low.

The determination made previously at the time of the problem formulation regarding risk resulting from this pathway remains unchanged and therefore risk to terrestrial organisms resulting from the storage of treated seed is expected to be below Agency levels of concern.

Terrestrial Exposure: Cattle Ear Tag Uses

Given the limited exposure to non-target terrestrial organisms associated with the spotty nature of cattle eartag uses of pirimiphos-methyl at pastureland use sites, risk quotients are not expected to exceed the LOCs for any non-target terrestrial organism.

5.2. Risk Description

This section discusses the potential for risks occurring to non-target aquatic organisms as a result of the washoff associated with pirimiphos-methyl eartag uses. As discussed in **Section 5.1**., a qualitative evaluation of the amount of heads of cattle resulting in a risk of concern to aquatic organisms is conducted (**Table 9**) as opposed to deterministic risk quotients given the uncertainty associated with the amount of simultaneous head of cattle treated. However, this section will place these estimates into context with what is known regarding the density of cattle only at pasture use sites. As discussed in **Section 2**, feedlots would not be use sites where pirimiphos-methyl eartags are used. Risks to other non-target organisms associated with eartag use or general ecological risks associated with other use patterns are not elaborated in this section since no risks of concern are expected as discussed in **Section 5.1.**

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Aquatic Exposure: Cattle Ear Tag Uses

As explained above, the amount of treated cattle resulting in a risk of concern to aquatic organisms is conducted (**Table 9**), and these results can be placed into context with information regarding cattle populations at pasture sites where pirimiphos-methyl eartags are potentially used. This information on cattle populations can inform and discern the potential number simultaneous heads of cattle treated with the eartags per use site. Cattle population data from USDA's AgCensus (citation: http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Ag_Atlas_Maps/Livestock_and_Animals/Livestock,_Poultry_and_Other_Animals/12-M136-RGBDot1-largetext.pdf) can be used for a preliminary estimate for cattle populations at use sites. **Figure 1** shows that up to 200 head of cattle or more are common over a high density of farms nationwide. While some sites may possess over 200 head of cattle, it is not anticipated that many of such sites would possess more than 300 head of cattle, as these numbers of cattle are more likely associated with major regulated feedlots under EPA's NPDES program, which as discussed in **Section 2**, feedlots would not be use sites where pirimiphos-methyl eartags are used. Furthermore, it is expected there would be many more sites less than 200 head of cattle, which would be the use sites where pirimiphos-methyl eartag treatments would be more likely. Sites that possess hundreds of heads of cattle would likely not possess the degree of horn fly and face fly infestations for the same reasons that eartags would not be used at feedlots as discussed in **Section 2**.

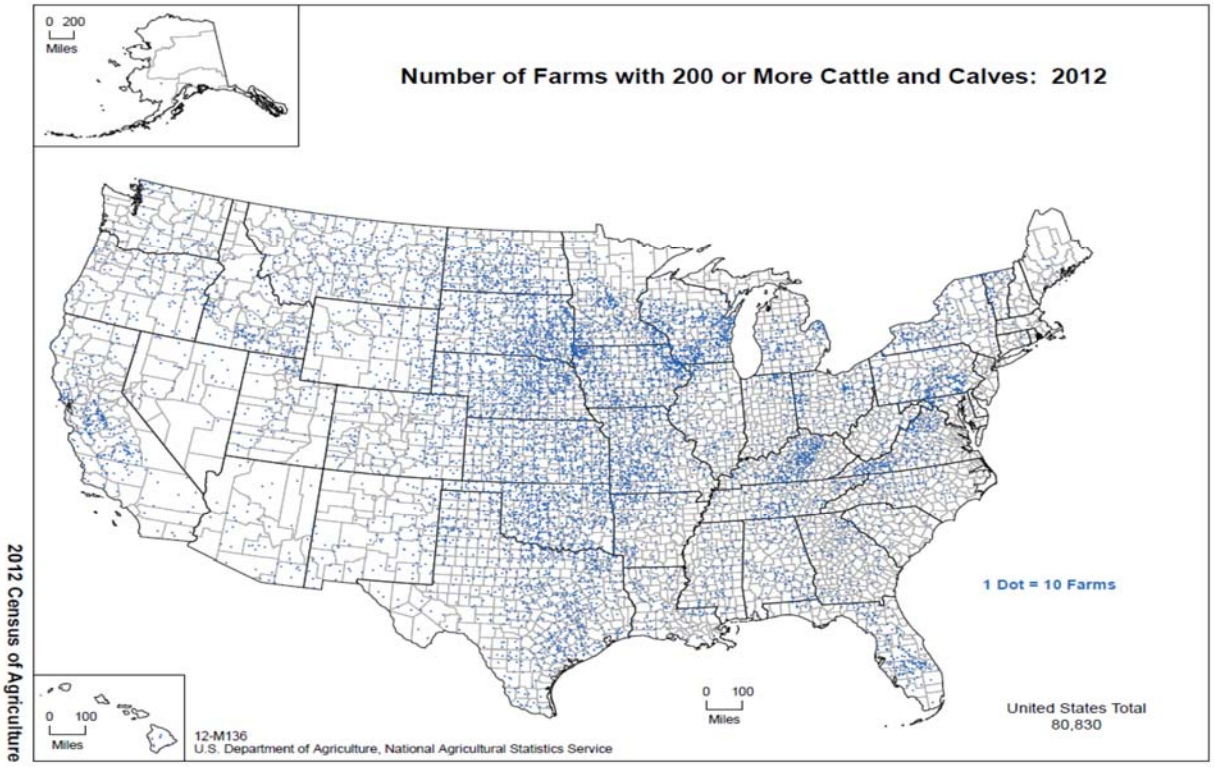

Figure 1. Dot density map showing approximate localities of farms keeping 200 or more head of cattle (Source: USDA AgCensus, 2012).

For non-listed and listed freshwater fish, **Table 9** shows that much more head of cattle than numbers of cattle at farms which possess less than 300 head of cattle (not associated with feedlots) would be required to result in adverse impacts on an acute basis. This is even the case if 100

percent of residues washoff from eartags. Therefore, no adverse impacts would be expected with eartag use associated with freshwater fish.

For non-listed freshwater invertebrates, **Table 9** also shows that more head of cattle than the number of cattle at non-feedlot farms would be required to result in acute adverse impacts with 10 percent or less of residues washing off from feedlots. In many cases, it would not be expected that less than 10 percent of pirimiphos-methyl residues would washoff and end up in water bodies for resosons further discussed in Uncertainties Section below. Therefore, adverse impacts would also not be expected with eartag use associated with non-listed freshwater invertebrates.

For listed freshwater invertebrate species, **Table 9** conveys that between 40 – 200 cattle can potentially result in acute adverse impacts with between 5 percent down to 1 percent, respectively, of residues washing off into a water body. However, as explained above, while some non-feedlot farms may keep in excess of 200 head of cattle, pirimiphos-methyl eartag use sites are not expected to be used at use sites keeping hundreds of head of cattle for reasons discussed in **Section 2**, and is therefore expected that pirimiphos-methyl would be most commonly used at sites keeping less than 40 head of cattle. According to the results presented in **Table 9**, greater than 5 percent of residues being washed off from eartags treating 40 head of cattle would lead to adverse impacts. However, it is expected that less than 5 percent of pirimiphos-methyl residues would wash off and end up in nearby water bodies for reasons discussed in the Uncertainties Section below. Therefore, in summary, no risks are anticipated for listed aquatic invertebrate species with pirimiphos-methyl eartag use which is expected to be used mainly at use sites keeping small inventories of cattle.

Uncertainties and Limitations

- **Acute Exposure of Pirimiphos-methyl and Washoff Fractions from Treated Cattle with Eartags**

While the results presented in **Table 9** provides a preliminary indication of the potential for risk associated pirimiphos-methyl eartags, the discussion below identifies uncertainties which exist regarding the fate and behavior of pirimiphos-methyl which are not explicitly captured in the analysis. The uncertainties in the analysis discussed below collectively provides insights that a small portion of residues (less than 5 percent) are likely to washoff and end up in water bodies nearby use sites with pirimiphos-methyl eartags.

1. The number of cattle and respective washoff fractions threshold for concern presented in **Table 9** is based on the assumption built into the GENEEC model that pirimiphos-methyl residues on the ear tag washes off within two days of the treatment off and runs off into a static water body. While possible, the washoff fraction would be even less in reality when rainfall events are delayed from the onset of eartag treatments given the potential for pirimiphos-methyl to degrade once it diffuses onto the skin of cattle.

2. Pirimiphos-methyl washoff and loadings in the underlying environment about the use site is likely to be reduced by a number of factors not captured in the analysis presented here. First, pirimiphos-methyl is semi-volatile with a vapor pressure 1.1×10^{-4} torr (**Table 1**), but the analysis did not account for any loss of residues due to volatilization. Second, this

assessment assumes that pirimiphos-methyl residues are not bound to the hide of treated cattle while rainfall occurs. In reality, there is the possibility that residues bound to treated cattle would further reduce the loadings of pirimiphos-methyl in the environment as compared to the washoff scenario presented in the analysis. It should be noted, however, that no data exists regarding the fate properties of pirimiphos-methyl on cattle skin and tissue.

Aside from washoff fractions potentially ending up in water bodies, the main underlying uncertainty in this assessment is related to the amount of cattle that are treated simultaneously with pirimiphos-methyl by use site. Labels do not specify limits for the amount of cattle that are treated with pirimiphos-methyl by use site. This uncertainty is addressed in the analysis by that it presents an evaluation of the number of heads of treated cattle leading to adverse impacts (*i.e.*, LOC exceedances) rather than deterministic risk quotients based on a rigid exposure scenario based on a fixed number of cattle treated with eartags. As explained in **Section 5.2**, given the density of cattle at pasture use sites and that only a percentage of those cattle would be treated, and that infestations of horn flies and face flies are not likely to occur at large industrial-scale farms, the amount of simultaneous heads of cattle treated with ceartags are expected to be less than 40 head over many cases.

- **Chronic Exposure with Pirimiphos-methyl Eartags and Associated Data Gaps**

As mentioned previously, there are no chronic data available for freshwater fish and estuarine/marine fish and invertebrates as well as to sediment dwelling organisms. Environmental fate data are only available to show abiotic routes of degradation of parent pirimiphos-methyl when in water bodies. The available hydrolysis study shows that at pH 7, parent pirimiphos-methyl has a half-life of 79 days. The rate of photodegradation in water is much faster with a half-life of 0.2 days. However, light penetration through water may not be significant in many cases. No information is available to indicate how parent pirimiphos-methyl would break down in a biotic aquatic system. Therefore, pirimiphos-methyl was only assumed to degrade abiotically (via hydrolysis and photolysis) and not biotically in the aquatic exposure analysis discussed in **Section 3.5**. Furthermore, consistent with other insect control type of applications, there are uncertainties related to frequency of applications. Therefore, these uncertainties related to the rate of degradation in water and pirimiphos-methyl application frequencies result in further uncertainties related to the duration of pirimiphos-methyl exposures persisting in aquatic environments.

While chronic toxicity studies are longer duration studies than acute studies, the intent of chronic studies is to expose organisms at different life stages than those of acute studies and below levels known to be lethal in order to elicit effects on growth and reproduction. It is anticipated due to the toxic nature of OP insecticides that chronic risk cannot be precluded to all aquatic taxa.

The suite of submitted studies for pirimiphos-methyl reveals that there was a submitted chronic daphnia life cycle study submitted in 1991. This study (MRID 48411701) is not associated with a data evaluation record (DER) and therefore its results are described here as they are not fully verified. Chronic daphnia were exposed to nominal concentrations of control, solvent control, 0.025, 0.05, 0.1, 0.2, and 0.4 µg a.i/L. There was total (100%) mortality in the two highest treatment concentrations, and 70% mortality in the 0.1 µg a.i/L treatment concentration. There

were no significant ($p<0.05$) reductions in length at all treatment concentrations (excluding the ones with 100% mortality for which no data were available). Additionally, there was a significant reduction in the total number of live young as compared to the control in the three highest treatment concentrations. The NOAEC for this study (based on live number of young and mortality) was therefore set at 0.05 µg a.i/L. As stated previously, these results are not statistically verified and therefore cannot be considered final but can be used qualitatively to indicate pirimiphos-methyl exposure appears to be an order of magnitude more toxic on a chronic basis as compared to an acute basis.

In extending the analysis for chronic data as it was presented for acute impacts in **Table 9** for all percent washoff scenarios assessed (1, 5, 10, 20, and 100%), the number of heads of cattle within a typical use site would result in similar amounts of treated cattle triggering risks of concern for aquatic invertebrates. Furthermore, similar washoff fractions for cattle densities presented in **Table 11** would result in risk of concerns for aquatic invertebrates considering the available chronic toxicity data. Therefore, given these similar outcomes, the above justification discounting risks of concern for acute aquatic invertebrates would also apply to chronic impacts.

- **Bioaccumulation of Pirimiphos-methyl**

As indicated by available environmental fate data, pirimiphos-methyl has the potential to bioaccumulate in the tissues of organisms based on its Log K_{OW} of 4.2. This is further corroborated by the bioconcentration factor (BCF) being estimated as 274X (SRC and EpiSuite, WSKOW v.1.42). While this potential exists, it is unclear, due to a lack of a registrant submitted fish BCF study, how quickly and to what extent pirimiphos-methyl residues are depurated from living tissues. Therefore, given the potential for pirimiphos-methyl's offsite transport to water bodies and its hydrophobic properties, pirimiphos-methyl has the potential to bioaccumulate in aquatic organisms like fish. The extent to which the consumption of those contaminated fish by birds will pose a risk is uncertain as a propensity to bioaccumulate does not necessarily indicate that those residues will be available in the tissues for days or weeks later.

Although GENEEC does not provide pore water EEC estimates, a run of the KABAM model using water column values provided by GENEEC is used to evaluate piscivorous birds including sandpipers, rails, and small osprey consuming pirimiphos-methyl contaminated fish. When assuming 20% washoff and subsequent runoff from 300 head of cattle getting treated at the same time, the highest RQ, occurring with dose-based risk to sandpipers eating pirimiphos-methyl contaminated fish remains, is below the listed species LOC (**RQ < 0.006**). Furthermore, there were no risk findings above the LOC for dose or dietary-based risk to mammals.

- **Terrestrial Exposure**

The exposure pathway for terrestrial organisms was determined to be minimal for the seed treatment stored grain use in the problem formulation of pirimiphos-methyl. Exposure to terrestrial organisms via the ear tag use was also determined to be minimal. Although acute and subacute dietary studies for birds indicate that pirimiphos-methyl is moderately to highly toxic to birds on both an acute oral and subacute dietary basis, and available data determined what doses and what concentrations would elicit lethal effects as well as clinical signs of toxicity, it is

unknown as to the extent of pirimiphos-methyl that would be available to terrestrial organisms. As mentioned previously the scenario of ear tags falling off heads of cattle was determined to not be likely and will therefore not be further discussed. That leaves few plausible scenarios as to how birds and other mammals would be exposed to pirimiphos-methyl resulting from this ear tag use. The lack of reported wildlife incidents to birds and other mammals for pirimiphos-methyl further suggest this pathway is potentially incomplete although the literature indicates birds and mammals may be an important vector for diseases transmission in cattle feed lots.

Pirimiphos-methyl is highly toxic to adult honey bees on an acute contact and oral basis as would be anticipated from an OP insecticide, although there are no data to characterize the toxicity to honey bee larvae. Additionally, there is an uncertainty as to what extent honey bees would be exposed to pirimiphos-methyl residues as cattle feedlots would likely not serve as attractive areas for forage.

- **Ecological Effects Data Gaps**

There are only three studies available to characterize the acute toxicity of pirimiphos-methyl to freshwater fish and invertebrates. The analysis presented above indicates that there is a plausible exposure pathway that can exist with at worst a 0.03% washoff threshold that is needed to cause impacts to listed freshwater invertebrates. While data are not available for estuarine/marine invertebrates, risk to this taxa cannot be precluded as washoff fractions could reach these environments, and as pirimiphos-methyl is an organophosphate insecticide, lethality to this taxa can be expected based on the extensive data set of other active ingredients.

There are also no data present to characterize the toxicity of pirimiphos-methyl to sediment dwelling aquatic invertebrates. Environmental fate data indicate pirimiphos-methyl has some propensity to bind to sediment as evidenced by its hydrophobic nature as evidenced by a Log K_{OW} of 4.2. Although no data are present, the case for the presence of risk to freshwater and estuarine/marine sediment dwelling invertebrates can be made based on the likelihood of some washoff of pirimiphos-methyl residues into aquatic systems and its propensity to bind to organic carbon. Furthermore, water column freshwater invertebrates were observed to be very sensitive to pirimiphos-methyl exposure as expected from an OP insecticide and so similar toxicity can be presumed to benthic invertebrates given that this exposure pathway cannot be precluded.

It was previously stated that no chronic toxicity data are available for birds. In a review of the submitted studies for pirimiphos-methyl, a study entitled "Egg Production and Hatchability Following Inclusion of Pirimiphos-methyl at Various Levels in the Diet of the Laying Hen," was found but was not associated with any DER. Therefore, the results of this study will be discussed here in the uncertainties section as they are not verified and therefore cannot be considered final at this time. This study (MRID 48361701) was conducted in 1978, which was prior to the availability of the current OCSPP 850.2300 avian reproduction study guideline. In the study, birds (species not identified) were exposed to pirimiphos-methyl concentrations in the diet of control, 4, 12, and 40 ppm. There were no treatment related mortalities that were observed nor were there any clinical signs of toxicity. There was no significant ($p<0.05$) reduction in food consumption that was observed in the treatment groups as compared to control although food consumption in the treatment groups were generally less than that of control. During the recovery period, food

consumption between the control and treatment groups was similar. There were no significant ($p<0.05$) reductions in egg production, fertility, and hatchability in the treatment groups as compared to control. The NOAEC for this study was therefore determined to be 40 ppm. As stated previously, it is not expected that birds would be subjected to exposure of pirimiphos-methyl resulting from the cattle eartag use.

- **Risk to Aquatic and Terrestrial Plants**

There is no data available to characterize the toxicity of pirimiphos-methyl to terrestrial and aquatic vascular and non-vascular plants. For terrestrial plants, exposure to this taxa would be limited for both stored grain seed treatment as well as for the ear tag use. As there are no spray uses for pirimiphos-methyl, non-target terrestrial plants would only be exposed via runoff from a feedlot. Given the mode of action of this chemical is the inhibition of cholinesterase, toxic effects to plants are not anticipated but there is uncertainty in toxicity to plants being mediated by some other mode of action. Furthermore, there are no reported ecological incidents with terrestrial plants and pirimiphos-methyl that provide some suggestion that this exposure pathway is potentially complete.

Risk to aquatic plants is a bigger uncertainty given that this exposure pathway would be complete via washoff from ear tags and the fact that there is no data available to characterize the toxicity to aquatic vascular and non-vascular plants.

6. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups.

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[10] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

Pirimiphos-methyl is not among the group of 58 pesticide active ingredients receiving EDSP test orders. For information on the status of the orders issued under the EDSP for each chemical, please visit our website at http://www.epa.gov/endo/ and click on the "Status of EDSP Orders/DCIs" in the Highlights Box. Additional information on the EDSP, including the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, can also be found at this website.

7. Federally Threatened and Endangered (Listed) Species of Concern

Based on this screening-level assessment, there are potential risks of direct effects to listed birds, mammals, freshwater and estuarine/marine fish, invertebrates, and sediment dwelling invertebrates, aquatic vascular plants, and terrestrial dicot plant species from the use of pirimiphos-methyl on some of its registered use sites. Listed species of birds, mammals, freshwater and estuarine/marine fish and invertebrate taxa may also be affected through indirect effects because of the potential direct effects on listed and non-listed species. Potential direct effects on listed birds, mammals, freshwater and estuarine/marine fish, invertebrates, and sediment dwelling invertebrates from the use of pirimiphos-methyl may be associated with modification of Primary Constituent Elements (PCEs) of designated critical habitats, where such designations have been made. However, at this current stage of the Registration Review process, it is premature to make effects determinations for listed species until further scientific analysis and refinements are conducted, based on recommendations received from the National Academy of Sciences' (NAS) National Research Council (NRC) April 2013 report, available at http://www.nap.edu/catalog.php?record_id=18344. The NAS report outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that are compliant with the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The EPA along with the U.S. Fish & Wildlife Service (USFWS), the National Marine Fisheries Service (NMFS) (collectively, the Services), and the U.S. Department of Agriculture (USDA), released a summary of their implementation plan for assessing risks of pesticides to listed species ahead of the stakeholder workshop held on November 15, 2013. This plan was developed in response to the NAS' recommendations, including a common approach to risk assessment as a way of addressing scientific differences between EPA and the Services. During the workshop, the agencies received feedback from the public on the interim scientific approaches that were

[10] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

developed as part of the initial implementation of the NAS recommendations. These approaches will be jointly implemented and vetted as part of a phased iterative process. Once fully vetted, EPA will further refine the listed species effects determination portion of this risk assessment.

To make effects determinations for individual listed species, useful refinements may include, but are not limited to, analyses of: 1) more detailed, species-specific ecological and biological data; 2) more detailed and accurate information on pirimiphos-methyl use patterns; and 3) sub-county level spatial proximity data for the co-occurrence of potential effects areas and listed species and any designated critical habitat. Examples of such refinements are described below.

EFED is currently developing tools that are expected to further refine the assessment and are designed to support effects determinations for individual federally listed species and their designated critical habitats (where applicable). Scientific information obtained from the Services, and other reliable sources is being collated by EFED to address all currently listed species. This information is being stored in an Office of Pesticide Programs (OPP) Pesticide Registration Information SysteM (PRISM) listed species knowledgebase. The listed species knowledgebase consists of an information repository that houses biological and behavioral information relevant to individual species (e.g., habitat, diet, and life history, including specific temporal and spatial associations) and a document repository that contains supporting documents (*e.g.*, USFWS recovery plans) and electronic information (*e.g.*, GIS data files). For terrestrial taxa, biological information relevant to the assessment (*e.g.*, diet and body weight) will be used to parameterize exposure estimates using a method consistent with currently used methods in the T-REX and T-HERPS models.

Refinements will also include more detailed analyses of the registered uses and specific use patterns that result in either "Likely to Adversely Affect" (LAA) or "Not Likely to Adversely Affect" (NLAA) determinations for federally listed species. The analyses may include more information on where, when, and how pirimiphos-methyl is used on all use sites. Actual usage data (when available) and national land-cover datasets that indicate potential use sites [*e.g.*, National Land Cover Dataset (NLCD), Cropland Data Layer (CDL)] may be used to support a more refined analysis of where pirimiphos-methyl is reasonably expected to be used. Similarly, refinements on the timing of applications and a more in-depth exploration of agronomic practices for pirimiphos-methyl may be included as part of the refinement.

The refinements based on individual species data; additional, detailed usage information, when available; and recommendations from the NRC report are expected to help to more accurately identify potential areas of effect and to better inform effects and habitat determinations for listed species and any designated critical habitats.

7.1 Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by pirimiphos-methyl use and not merely the immediate area where pirimiphos-methyl is applied. At the initial screening-level, the risk assessment considers broadly described taxonomic groups and conservatively estimates exposure for organisms that are co-located with the pesticide treatment area. This means that terrestrial plants and wildlife are assumed to be

located on or adjacent to the treated site and aquatic organisms are assumed to be located in a surface water body adjacent to the treated site, except in the case of direct application to aquatic habitat.

[3]No data are available on terrestrial and aquatic plants which may serve as food items for all terrestrial and aquatic taxa. It is unclear of the toxicity of pirimiphos-methyl to these taxa and in the case of terrestrial plants, as to whether a complete exposure pathway would exist given the absence of spray uses of pirimiphos-methyl.

[4]Although no toxicity data are available, the acute and chronic toxicity to these taxa to OP insecticides is well established as well as the fact that pirimiphos-methyl is stable to aerobic aquatic metabolism.

7.2 Listed Species Occurrence Associated with Registered Uses

The screening-level risk assessment for pirimiphos-methyl assumes that it may be applied nationwide, including U.S. territories and possessions. Therefore, no federally listed species are excluded from the screening level analyses, unless otherwise indicated (*e.g.*, if only listed due to Similarity of Appearance to another listed species). A spatial co-occurrence analysis that compares the best available data regarding pirimiphos-methyl potential and documented use areas and listed species occurrence is needed to more explicitly address potential risk to listed species of concern. The Agency has requested data to support this analysis from the Federal Endangered Species Task Force (FESTF).

8. Conclusions

There are many uncertainties related to pirimiphos-methyl, several of which were detailed in the Risk Description Section of this assessment. These uncertainties mainly relate to environmental fate and ecological effects data gaps, as well as the unconventional nature of the uses associated with pirimiphos-methyl where exposure cannot be estimated in a conventional manner using standard EFED models. However, given the highly conservative nature of the assumptions for environmental loading as provided in this assessment, and that small cattle operations are where pirimiphos-methyl eartags are only used, exposure is not expected to occur at levels exceeding levels of concern to aquatic or terrestrial organisms.

9. References

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Appendix A. Environmental Fate and Ecological Effects Data for Pirimiphos-methyl

161-1 Hydrolysis

MRID	Citation Reference
135353	ICI Americas, Inc. (1977) Actellic 7E Insecticide: ?Product Chem- istry|. (Compilation; unpublished study received Dec 1, 1978 under 10182-EX-15; CDL:097668-A)
135356	Easton, C.; Seaman, D. (1970) Pyrimidines: Effect of pH on the Hydrolysis of PP 211 and PP 511: Ref. No. AR 2175 A. (Unpub- lished study received Dec 1, 1978 under 10182-EX-15; prepared by Plant Protection Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL:097680-A)
135357	Bowker, D.; Hughes, H. (1974) Pirimiphos-methyl: Fate in Water: AR 2516A. (Unpublished study received Dec 1, 1978 under 10182-EX- 15; prepared by Plant Protection Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL:097680-B)
42982401	Hall, B. (1993) The Determination of the Hydrolytic Stability of (carbon 14)-Pirimiphos-Methyl: Lab Project Number: 9545: 382403. Unpublished study prepared by Inveresk Research International. 112 p.
43177601	Hall, B.; Williams, S. (1994) **Report Amendment to Study Report (MRID # 42982401)**: The Determination of the Hydrolytic Stability of (carbon 14)-

	Pirimiphos-Methyl: Lab Project Number: 382403: WECO-9206: 9545 ADDENDUM. Unpublished study prepared by Inveresk Research International. 37 p.

162-1 Aerobic soil metabolism

MRID	Citation Reference
135358	Arnold, D.; Hill, I.; Harvey, B.; et al. (1976) Pirimiphos-methyl: Degradation of the Pesticide in Soil under Laboratory Condi- tions: AR 2656 A. (Unpublished study received Dec 1, 1978 under 10182-EX-15; prepared by Imperial Chemical Industries, Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL: 097680-D)

163-1 Leach/adsorption/desorption

MRID	Citation Reference
68104	Riley, D.; Stevens, J.E. (1975) Pirimiphos-ethyl: Leaching in Soil: AR 2592A. (Unpublished study received Dec 17, 1976 under 10182-9; prepared by Plant Protection Ltd., submitted by ICI Americas, Inc., Wilmington, Del.; CDL:227314-W)
48355602	Schocken, M. (2010) Acceptability of Foreign Soils Used in a Pirimiphos-Methyl Batch Equilibrium Study. Project Number: 2010/P/3. Unpublished study prepared by Schocken Consulting, LLC. 23 p.
48355601	Hartfree, Y.; Muller, K.; Lane, M. (2011) Pirimiphos-Methyl: Adsorption and Desorption in Soil. Project Number: RJ1461B. Unpublished study prepared by Jealott's Hill Res. Station. 70 p.

164-1 Terrestrial field dissipation

MRID	Citation Reference
154033	Heuer, B.; Birk, Y.; Yaron, B. (1976) Effect of phosphatases on the persistence of organophosphorus insecticides in soil and water. **Journal of Agric. Food Chem. 24(3):611-614.**

Non-Guideline Studies

MRID	Citation Reference
44053301	Hathorn, S. (1996) Nu-Gro Insecticide S.P...: Response to EPA Chemistry Branch Review of

	Data Requirements to Defend the Use on Corn Seed and Sorghum Seed for Controlling Storage Pests: Lab Project Number: DEFENSE OF BULK/BAGGED SEED USE RESPONSE. Unpublished study prepared by Compliance Services International. 129 p.
44584702	Sielaty, R. (1998) Pirimiphos-Methyl in vitro Absorption from a 500g/l EC Formulation through Rat Epidermis: Lab Project Number: WECO-9802: JV1483: CTL/P/5239. Unpublished study prepared by Compliance Services International. 27 p.
45932601	Wo, C. (2003) UV/Visible Absorption: Pirimiphos-methyl Technical: Lab Project Number: 13425: P805. Unpublished study prepared by Product Safety Labs. 13 p. {OPPTS 830.7050}
46173801	Lake, R. (2004) Product Chemistry: Storage Stability and Corrosion Characteristics: Dominator Insecticide Ear Tags. Project Number: 071/006, EXP/071/006, EXM/071/004. Unpublished study prepared by Exygen Research. 56 p

71-1 Avian Single Dose Oral Toxicity

MRID	Citation Reference
41311001	Ross, D.; Roberts, N.; Fairley, C. (1979) The Acute Oral Toxicity (LD50) of Pirimiphos Methyl to the Mallard Duck: Lab Project Number: CTL/C/726. Unpublished study prepared by Imperial Chemical Industries Ltd., Huntingdon Research Centre. 18 p.
43442101	Campbell, S.; Beavers, J. (1994) Pirimiphos-Methyl: An Acute Oral Toxicity Study With the Northern Bobwhite: Lab Project Number: 94041-WECO: 134-103. Unpublished study prepared by Wildlife International Ltd. 59 p.
80742	Gage, 1971. Oral with Green finch, Pigeon, and Japanese quail. Accession 097679.

71-2 Avian Dietary Toxicity

MRID	Citation Reference
42037001	Hakin, B.; Johnson, A.; Anderson, A.; et al. (1990) Pirimiphos- Methyl Dietary Toxicity (LD50) to the Bobwhite Quail: Lab Proj- ect Number: JAN 244/90755. Unpublished study prepared by Hunt- ingdon Research Centre, Ltd. 30 p.
103923	Parkinson, G.; Banham, P. (1971) Pirimiphos-methyl (PP 511): Avian Toxicity: Report No. HO/1H/R/329. (Unpublished study received Dec 1, 1978 under 10182-EX-15; prepared by Imperial Chemical Industries, Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL:097679-B)
107422	Fink, R. (1974) Final Report: Eight-day Dietary LC50--Mallard Ducks: ?Technical Pirimiphos Methyl|: Project No. 123-102. (Unpublished study received Dec 1, 1978 under 10182-EX-15; prepared by Truslow Farms, Inc., submitted by ICI Americas, Inc., Wilmington, DE; CDL:097679-D)
107423	Fink, R. (1974) Final Report: Eight-day Dietary LC50--Bobwhite Quail:

	?Technical Pirimiphos Methyl|: Project No. 123-101. (Unpublished study received Dec 1, 1978 under 10182-EX-15; prepared by Truslow Farms, Inc., submitted by ICI Americas, Inc., Wilmington, DE; CDL:097679-E)

72-1 Acute Toxicity to Freshwater Fish

MRID	Citation Reference
92147004	Smyth, D.; Hill, R. (1990) ICI Americas Inc. Phase 3 Summary of MRID 00103924. Pirimiphos-methyl (PP511): Determination of the Acute Toxicity to Rainbow Trout (Salmo gairdneri): Report No. BL/B/1868; Study No. D608/A. Prepared by ICI BRIXHAM LABORATORY. 12 p.
103925	Bluegill Acute Brixham Laboratories, 1975
103925	Rainbow Acute Brixham Laboratories, 1975
103924	Hill, R. (1978) Determination of the Acute Toxicity of Pirimiphos- methyl to Rainbow Trout ...: BL/B/1868. (Unpublished study received Dec 1, 1978 under 10182-EX-15; prepared by Imperial Chemical Industries, Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL:097679-F)
108078	Hill, R. (1978) Determination of the Acute Toxicity of Pirimiphos- methyl to Fathead Minnow ...: BL/B/1873. (Unpublished study received Dec 1, 1978 under 10182-EX-15; prepared by Imperial Chemical Industries, Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL:097679-G)

72-2 Acute Toxicity to Freshwater Invertebrates

MRID	Citation Reference
92147005	Hamer, M. (1990) ICI Americas Inc. Phase 3 Summary of MRID 00103926. Pirimiphos-methyl: Toxicity to First Instar Daphnia magna: Report No. TMJ1411B. Prepared by ICI AGROCHEMICALS. 13 p.
103926	Pirimiphos-methyl: Toxicity to First Instar Daphnia magna: Report No. TMJ1411B. Prepared by ICI AGROCHEMICALS. 13 p. Test includes technical and formulation testing

850.1300 Chronic Toxicity Freshwater Invertebrates

MRID	Citation
48417101	Rapley, J.; Hamer, M. (1991) Pirimiphos-Methyl: Chronic Toxicity to Daphnia magna. Project Number: RJ0940B. Unpublished study prepared by ICI Agrochemicals. 29 p.

141-1 Honeybee Acute Toxicity Testing

MRID	Citation Reference

05001991	Stevenson, 1978. Bee studies conducted at Univ. of California

142-3 Simulated or Actual Field Testing

MRID	Citation Reference
43717	Smith, F.D. (1976) PP557: Effects on Predatory and Parasitic Arthropods: Report Series TMJ 1283 B. (Unpublished study received Dec 2, 1976 under 10182-EX-3; prepared by Imperial Chemi- cal Industries, Ltd., submitted by ICI Americas, Inc., Wilmington, Del.; CDL:095996-G)
50011991	Stevenson, J.H. (1976). The acute toxicity of unformulated pesticides to worker honey bees (Apis mellifera L.). Plant Pathol. 27(1): 38-40.

Non-Guideline Study

MRID	Citation Reference
46364315	Brealey, C.; Walker, C.; Baldwin, B. (1980) A-Esterase Activities in Relation to the Differential Toxicity of Pirimiphos-Methyl to Birds and Mammals. Pestic. Sci. 11: 546-554.

Appendix B. Aquatic Exposure Modeling Summary

Figure B-1. GENEEC model run for pirimiphos-methyl eartag uses.

```
RUN No.   1 FOR Pirimiphos-methy ON   eartags       * INPUT VALUES *
   ---------------------------------------------------------------------
   RATE (#/AC)   No.APPS &   SOIL  SOLUBIL   APPL TYPE  NO-SPRAY INCORP
    ONE(MULT)    INTERVAL     Kd   (PPM )    (%DRIFT)   ZONE(FT)  (IN)
   ---------------------------------------------------------------------
  1.000(  1.000)   1   1      49.0    8.6   GRANUL(  0.0)   0.0   0.0


   FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)
   ---------------------------------------------------------------------
   METABOLIC  DAYS UNTIL  HYDROLYSIS   PHOTOLYSIS   METABOLIC  COMBINED
```

(FIELD)	RAIN/RUNOFF	(POND)	(POND-EFF)	(POND)	(POND)
39.10	2	198.00	0.20-	24.80	0.00	22.04

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
7.26	6.97	5.60	3.62	2.75

Notes:

1. Please refer to **Table 2** for explanation and rationale for input parameter values.
2. Modeling conducted normalized to an application rate of 1 lb. a.i./A. Results shown in **Tables 8 and 9** are derived from linearly scaling the peak EEC shown in this figure to the application rates per head of cattle shown in **Table 8** for each washoff fraction.

Appendix C. Inhalation Exposure Screening Evaluation

Figure C-1. STIR run for pirimiphos-methyl eartag and seed treatment uses.

This tool is designed to provide the risk assessor with a rapid method for determining the potential significance of the inhalation exposure route to birds and mammals in a risk assessment.

Input		
Application and Chemical Information		
Enter Chemical Name	Pirimiphos-methyl	
Enter Chemical Use	Eartag	
Is the Application a Spray? (enter y or n)	n	
If Spray What Type (enter ground or air)	ground	
Enter Chemical Molecular Weight (g/mole)	305	
Enter Chemical Vapor Pressure (mmHg)	1.10E-04	
Enter Application Rate (lb a.i./acre)		
Toxicity Properties		
Bird		
Enter Lowest Bird Oral LD_{50} (mg/kg bw)	40	
Enter Mineau Scaling Factor	1.15	
Enter Tested Bird Weight (kg)	0.178	
Mammal		
Enter Lowest Rat Oral LD_{50} (mg/kg bw)	2400	
Enter Lowest Rat Inhalation LC_{50} (mg/L)	5.04	
Duration of Rat Inhalation Study (hrs)	4	
Enter Rat Weight (kg)	0.35	
Output		
Results Avian (0.020 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	1.81E+00	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	2.27E-01	
Adjusted Inhalation LD_{50}	4.68E-01	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	4.85E-01	**Proceed to Refinements**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	not applicable	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	not applicable	**not applicable**
Results Mammalian (0.015 kg)		
Maximum Vapor Concentration in Air at Saturation (mg/m^3)	1.81E+00	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	2.85E-01	
Adjusted Inhalation LD_{50}	3.00E+02	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	9.51E-04	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	not applicable	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	not applicable	**not applicable**

Figure C-2. HED Tier 1 Air Exposure Model run for pirimiphos-methyl eartag and seed treatment uses.

Pirimiphos-Methyl													
Vapor Pressure (Pa)	1.10E-04							Distance to COC (m)					
Solubility (mg/L)	8.6						Field Size (acres)	10	20	40	60	80	120
Koc (ml/g)	3329					Crop Type	Bare soil	0	0	0	0	0	N/A
	Bare soil	Foliar apps to crops					Cole crop	0	0	0	0	0	N/A
Application rate (lbs ai/A)	2.744	NA					Row crop	0	0	0	0	0	0
Hourly Flux Rate (µg/m^2-s)	8.10E-02	2.61E-02					Orchard[1]	0	0	0	0	0	N/A
Application timing	Worst case												
Averaging time for concentration (hours)	1												
Inhalation POD (µg/m^3)	930.75												
UF (unitless)	10												
Concentration of concern (µg/m3)	93												
Notes:													
1. Air flow through an orchard is complex and AERSCREEN does not take this complexity into account.													
Orchard values should be characterized appropriately.													
2. Areas shaded in green are for user input. The user should not enter information in the areas shaded in red.													
3. "Duration of maximum emission" should be less than or equal to 24 hours.													

* Equivalent application rate calculated assuming 8,000 head of cattle present on 10 ha feedlot.

Figure C-3. HED Tier 1 Air Exposure Model estimated exposure concentrations for vapor-phase pirimiphos-methyl.

	Bare soil				
Distance (m)	10	20	40	60	80
0	10.26	17.34	26.68	33.12	38.46
5	10.56	17.64	26.92	33.33	38.73
10	10.85	17.94	27.16	33.60	38.99
15	11.14	18.24	27.40	33.86	39.26
20	11.43	18.53	27.67	34.13	39.53
25	11.73	18.83	27.96	34.40	39.78
50	13.24	20.38	29.39	35.69	40.91
75	14.47	21.44	30.54	37.27	42.28
100	15.25	22.06	31.09	37.84	43.21
125	15.66	22.37	31.48	38.08	43.31
150	15.80	22.54	31.62	38.08	43.19
175	15.83	22.61	31.55	37.89	42.96
200	15.80	22.53	31.34	37.57	43.26
225	15.71	22.34	31.06	37.76	43.44
250	15.55	22.08	30.93	37.88	43.48
275	15.33	21.77	31.01	37.87	43.41
300	15.08	21.64	30.98	37.78	43.25
325	14.86	21.63	30.88	37.60	43.02
350	14.77	21.55	30.73	37.37	42.79
375	14.71	21.43	30.52	37.15	42.53
400	14.60	21.27	30.29	36.89	42.23
425	14.48	21.09	30.05	36.61	41.89
450	14.33	20.89	29.82	36.30	41.54
475	14.17	20.70	29.55	35.97	41.16
500	14.00	20.50	29.26	35.63	40.77

Notes:

1. Maximum EEC shown in yellow shading.

Appendix D. Drinking Water Exposure Screening Evaluation

Table C-1. SIP model run for pirimiphos-methyl.

Parameter	Value
Chemical name	Pirimiphos-methyl
Solubility (in water at 25ºC; mg/L)	8.6
Mammalian LD_{50} (mg/kg-bw)	2400
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Mammalian NOAEL (mg/kg-bw)	0.87
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Avian LD_{50} (mg/kg-bw)	40
Avian test species	northern bobwhite quail
Body weight (g) of "other" avian species	
Mineau scaling factor	1.15
Mallard NOAEC (mg/kg-diet)	
Bobwhite quail NOAEC (mg/kg-diet)	
NOAEC (mg/kg-diet) for other bird species	
Body weight (g) of other avian species	
NOAEC (mg/kg-diet) for 2nd other bird species	
Body weight (g) of 2nd other avian species	

Table 2. Mammalian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	1.4792	1.4792
Adjusted toxicity value (mg/kg-bw)	1845.9854	0.6692
Ratio of exposure to toxicity	0.0008	2.2105
Conclusion*	**Drinking water exposure alone is NOT a potential concern for mammals**	**Exposure through drinking water alone is a potential concern for mammals**

Table 3. Avian Results

Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	6.9660	6.9660
Adjusted toxicity value (mg/kg-bw)	28.8172	0.0000
Ratio of exposure to acute toxicity	0.2417	0.0000
Conclusion*	**Exposure through drinking water alone is a potential concern for birds**	**Due to insufficient data, risk cannot be precluded**

*Conclusion is for drinking water exposure alone. This does not combine all routes of exposure. Therefore, when aggregated with other routes (*i.e.*, diet, inhalation, dermal), pesticide exposure through drinking water may contribute to a total exposure that has potential for effects to non-target animals.

Appendix E. Degradates Summary for Pirimiphos-Methyl

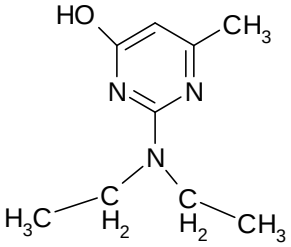
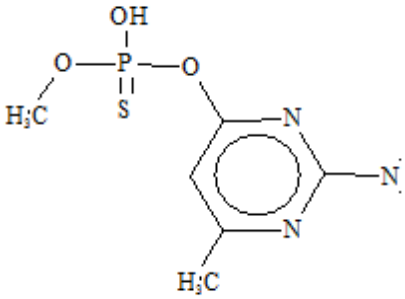
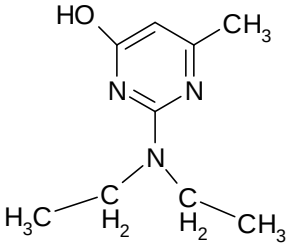
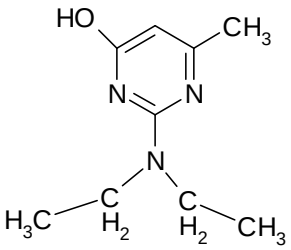
Table E-1. Pirimiphos-methyl degradation products identified in environmental fate studies.			
Degradate Identity	**Structure**	**Max% of Applied and Days Post Application**	**Comments**
Hydrolysis (MRID Nos. 42982401 and 43177601)			
2(diethylamino)-4-hydroxy-6-methyl pyrimidine (**Non-OP degradate**)		87.25%, 30 days (pH5) 22.51%, 90 days (pH7) 29.97%, 60 days (pH9)	pH5 study terminated at 30 days. pH7 study terminated at 90 days. pH9 study terminated at 60 days.
O-2 diethylamino-6-methylpyrimidin-4-yl o-methyl-phosphorothioate (**OP Demethylated degradate**)		4.99%, 21 days (pH5) 26.54%, 90 days (pH7) 18.17%, 60 days (pH9)	pH5 study terminated at 30 days. pH7 study terminated at 90 days. pH9 study terminated at 60 days.
Aerobic Soil Metabolism (MRID No. 135358)			
2(diethylamino)-4-hydroxy-6-methyl pyrimidine (**Non-OP degradate**)		42.08%,, Peartree Sandy Loam (SL1) at 70 days 55.58%,, Frensham Sandy Loam (SL2) at 14 days 37.22%,, Gore Loam (L) at 14 days 66.28 %,, Blackborough Peat (P) at 210 days	Studies in all soils terminated at 210 days.

Table E-1. Pirimiphos-methyl degradation products identified in environmental fate studies.			
Degradate Identity	**Structure**	**Max% of Applied and Days Post Application**	**Comments**
Anaerobic Soil Metabolism (MRID No. 135358)			
2(diethylamino)-4-hydroxy-6-methyl pyrimidine (**Non-OP degradate**)		61.4%,, Peartree Sandy Loam (SL1) at 14 days 37.22%,, Gore Loam (L) at 14 days	Studies in all soils terminated at 210 days. Findings from flooded water soil atmosphere reported.